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Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry

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This document is an economic impact assessment of the effluent guidelines recently promulgated for the pharmaceutical industry, as well as guidelines proposed for new direct dischargers. The report is being distributed to EPA Regional Offices and state pollution control agencies and directed to the staff responsible for writing industrial discharge permits. The report includes detailed information on the costs and economic impacts of various treatment technologies. It should be helpful to the permit writer in evaluating the economic impacts on an industrial facility that must comply with BAT limitations or water quality standards.

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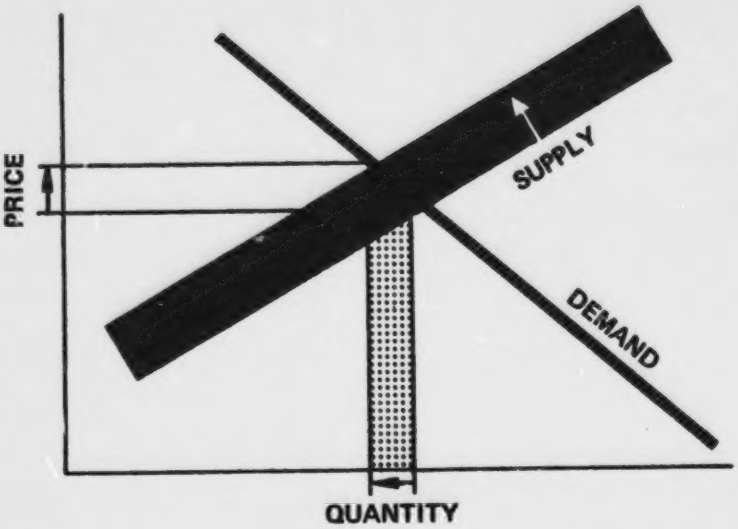

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The report is also being distributed to EPA Regional Libraries, and copies are available from the National Technical Information Service (NTIS), 5282 Port Royal Road, Springfied, Virginia 22161 (703/487-4600).

If you have any questions about this report, or if you would like additional information on the economic impact of the regulation, please contact the Economic Analysis Staff in the Office of Water Regulations and Standards at EPA Headquarters:

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Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry

U.S. Environmental Protection Agency
Office of Analysis and Evaluation
Washington, DC 20460

September 1983

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Preface

The attached document is a contractor's study prepared for the Office of Water Regulations and Standards of the Environmental Protection Agency ("EPA"). The purpose of the study is to analyze the economic impact which could result from the application of alternative BPT, BAT, PSES, NSPS and PSNS limitations and standards established under the Federal Water Pollution control Act (the Act), as amended.

The study supplements the technical studies ("EPA Development Documents") supporting the proposal and issuance of regulations under the Act. The Development Documents survey existing and potential waste treatment control methods and technology within particular industrial source categories and support proposed limitations based upon an analysis of the feasibility of these limitations in accordings with the requirements of the Act. Presented in the Development Documents are the investment and operating costs associated with various alternative control and treatment technologies. The attached document supplements this analysis by estimating the broader economic effects which might result from the required application of various control methods and technologies. This study investigates the effect of alternative approaches in terms of price increases, effects upon employment and the continued viability of affected plants, and other competitive effects.

The study has been prepared with the supervision and review of the Office of Analysis and Evaluation of the EPA. This report was submitted in fulfillment of Contract No. 68-01-6162, by Meta Systems Inc. This report reflects work completed as of September 1983.

This report is being released and circulated at approximately the same time as publication in the Federal Register of two notices pertaining to the pharmaceutical industry. The first notice relates to proposed NSPS for BOD_5 and TSS and the second to final BPT, BAT, PSES, NSPS (cyanide) and PSNS limitations and standards.

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Section 1

Executive Summary

Introduction

As required by the Clean Water Act, this study presents an analysis of the economic effects of effluent limitations and standards on the pharmaceutical industry. This study was prepared under the supervision of the Office of Analysis and Evaluation, U.S. Environmental Protection Agency. This Executive Summary presents brief descriptions of the other sections of the report. These include:

- Effluent Limitations and Standards
- Industry Profile
- Economic Impact Methodology
- Economic Impact Results
- New Source Performance Standards
- Regulatory Flexibility Analysis
- Limits to the Analysis

The study is based on data from various sources. The Technical Contractor provided estimated treatment costs for each plant under each regulatory option analyzed. Employment for each plant was taken from the EPA technical survey. Sales for most plants were provided by Economic Information Systems, Inc. (EIS). For a few of the single-establishment firms, plant sales were provided by Dun and Bradstreet. For the remaining plants, sales were estimated on the basis of employment. Information on products came from a variety of sources, including the EPA technical survey, the 1979 Directory of Chemical Producers, state manufacturing guides and studies by other contractors. Company-level financial data were drawn from annual reports and/or 10-K reports. Company product information came from a variety of trade and professional publications, and market studies. Industry-wide information came from academic studies, trade publications, market studies, and the U.S. Census of Manufactures: SIC groups 2831, 2833 and 2834.*

Effluent Limitations and Standards

This report analyzes the following regulatory options:

- BPT control of cyanide and revision of the TSS limitations for direct discharging plants,

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* See Section 4, Methodology, for a more complete discussion of data sources.

- BAT limitations for direct discharging plants,

  Option 1: Limits the discharge of cyanide,
  Option 2: Limits the discharge of cyanide and methylene chloride.

- PSES limitations for indirect discharging plants,

  Option 1: Limits the discharge of cyanide,
  Option 2: Limits the discharge of cyanide and methylene chloride.

- NSPS for new direct discharging plants. In addition to limitations for pH and cyanide:

  Option A: Limitations for BOD_5 and TSS based on advanced biological treatment,
  Option B: Limitations for BOD_5 and TSS based on advanced biological treatment plus filtration.

- PSNS control for new indirect discharging plants, with cyanide limits set equal to PSES.

BCT, which will cover BOD_5 and TSS limitations for direct dischargers, is being addressed in a separate regulation. Regulation of COD under BAT and NSPS is being deferred.

Industry Profile

The U.S. pharmaceutical industry has been defined by EPA as all establishments producing: biological products classified in Standard Industrial Classification (SIC) 2831; medicinals and botanicals classified in SIC 2833; pharmaceutical preparations classified in SIC 2834; other pharmaceutically active products not covered by SICs 2831, 2833, and 2834; cosmetic preparations in SIC 2844 which function primarily as a skin treatment; and products with multiple end uses at least one of which is as a component of a pharmaceutical preparation.

U.S. Census of Manufactures data indicate the total value of shipments in 1977 for pharmaceutical establishments classified in SICs 2831, 2833, and 2834 were $14.2 billion with value added equal to $9.9 billion. Value added was one-half of one percent of the $1.9 trillion GNP in that year. Establishments in those SICs employed 80.3 thousand production workers and 156.5 thousand workers overall.

The industry definition covers the production of both bulk pharmaceuticals (active ingredients) and final pharmaceutical products. The final products of the pharmaceutical industry can be divided into eleven major market areas. Between 1972 and 1977, the average annual growth rate of all eleven groups was 9.3 percent. The group which experienced the most vigorous growth was the vitamins, nutrients, and hematinics category at 17.3 percent annually with shipments of $1.3 billion in 1977. Preparations affecting parasitic and infectious diseases showed the slowest annual growth at 6.3 percent with shipments of $1.3 billion. The 1977 value of shipments of each of the eleven final product groups ranged from $126 million for active and passive immunization agents and therapeutic counterparts to $2.2 billion for preparations affecting the central nervous system and sense organs.

The industry cost structure is characterized by large expenditures on R&D and marketing. Approximately 8 percent and 24 percent of sales revenues are directed towards R&D and marketing respectively. Before-tax profits average about 15 percent of pharmaceutical sales; and after-tax profits as a percent of sales are between two and three times the average for other industries.

Pharmaceutical products have two characteristics which effect the price elasticities, level of competition, and market structure. First, for the large number of pharmaceutical products which are patented, competition is greatly reduced and cost increases can be passed on relatively easily in the form of price increases. Second, ethical drugs make up a large percentage of total sales. Since ethical drugs require a prescription, the medical profession influences both total demand and product choice.

The Food and Drug Administration (FDA) has established an approval process in order to insure the safety and effectiveness of drugs entering the market. Additional government involvement is found in the form of tax incentives, patent and trademark systems, and generic substitution laws.

Both foreign involvement in the U.S. pharmaceutical industry and U.S. involvement in world pharmaceutical markets are significant. In 1977, the U.S. was the largest consumer and the second largest net exporter of pharmaceuticals. Foreign involvement in our domestic industry takes the form of imports, partial ownership of U.S. firms, and domestic manufacturing facilities owned by foreign firms.

Economic Impact Methodology

Using a demand/supply analysis for each product sector, the economic impacts of the proposed water pollution regulations could be measured in terms of changes in price and production levels. Two barriers preclude such an analysis for the pharmaceutical industry: lack of detailed data and the absence of certain basic market characteristics required for the demand/supply analysis (in particular, a competitive market). As an alternative, the methodology assesses the likelihood of establishment closure due to compliance costs. First, all plants are screened to select those plants which are likely to have significant impacts. Those establishments identified by screening are examined in greater detail.

EPA surveyed the industry in the form of a technical 308 Survey. From the responses, 466 manufacturing facilities were identified, of which 55 were direct discharges and 277 were indirect dischargers, with the remaining plants zero dischargers (including such methods as deep-well injection). The Technical Contractor provided estimates of annual treatment cost for each plant under each proposed regulatory option. See their reports for a detailed description of the development of these cost estimates. The economic impact analysis is based on this sample of 466 plants and their estimated costs.

The screening measure compares estimated annual incremental treatment cost of the regulation to establishment sales. If an establishment incurs costs greater than one percent of sales, further investigation was considered necessary. Because of the high ratio of after-tax profits to sales in the industry (over 11 percent), treatment costs less than one percent of sales seemed manageable. Sales data for 202 out of 466 plants were not available. Sales for these plants were estimated based on their reported manufacturing employment and a regression of sales against manufacturing employment for similar establishments with data.

After screening, each establishment identified by the cost-to-sales ratio was examined further. Financial position and lines of business of the parent company along with information on products produced, market positions, and similar data on the establishment itself, contributed to a final assessment of the establishment's ability to absorb and/or pass through treatment costs.

Economic Impact Analysis

Best Practicable Control Technology Currently Available (BPT)

An estimated eight (8) out of the 55 direct dischargers in the 308 sample of 466 establishments may incur costs under these limitations. The total cost of compliance (in 1982 dollars*) is:

	BPT
Total capital cost	$1,049,000
Total annual cost	$ 412,000

No plant closures or significant impacts are expected from this BPT limitation.

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*Section 5 uses 1980 dollars. For comparison purposes, costs are escalated to 1982 dollars in the Executive Summary, by multiplying 1980 costs by 1.152. This factor is based on the ENR Construction Cost Index.

Best Available Technology Economically Achievable (BAT)

An estimated nine (9) direct dischargers may incur costs under the BAT Option 2 limitations. The total cost of compliance (in 1982 dollars) is:

	Option 1	Option 2
Total capital costs	zero	$6,625,000
Total annual costs	zero	$6,437,000

The total annual cost for Option 2 includes a credit of $121,000 for the methylene chloride that is recovered from the wastewater treatment system.

No plant closures or significant impacts are expected from the BAT Option 2 limitations.

Pretreatment Standards for Existing Sources (PSES)

There are two options for the PSES regulation. Option 1 limits cyanide concentrations only, and PSES Option 2 limits cyanide and methylene chloride. One plant would incur costs under Option 1. An estimated twenty-five (25) plants out of 277 indirect dischargers will incur costs under Option 2. The total cost of compliance for these options (in 1982 dollars) is:

	PSES Option 1	PSES Option 2
Total capital cost	$415,000	$19,086,000
Total annual cost	$257,000	$18,765,000

The total annual cost for Option 2 includes a credit of $686,000 for the methylene chloride that is recovered from wastewater treatment system.

It is not expected that any plants would close under Option 1. It is estimated that one plant might close due to Option 2. If the plant does close, 81 employees could be affected. This represents 0.09 percent of the total employment of indirect discharging plants. Price increases and balance of trade impacts are expected to be very small.

New Source Performance Standards (NSPS)

The effluent limitations under the NSPS options analyzed here are more stringent than those for existing sources and consequently costs are higher. The incremental annual treatment cost beyond BPT, as a ratio to plant sales, ranges from 0.02 to 0.5 percent for Option A and 0.1 to 0.9 percent for Option B. Either of the two options would be expected to have little or no impact on entry or construction in the industry.

Pretreatment Standards for New Sources (PSNS)

Since the limitations for the PSNS option are the same as those for existing sources (PSES), there are no incremental costs.

Resource Conservation and Recovery Act (RCRA)

RCRA costs were not analyzed because the sludge generated under the limitations for existing sources, as well as that to be generated as a result of the new source regulations, is not hazardous and therefore not subject to RCRA regulations.

Regulatory Flexibility Analysis

The differential impact on small businesses was analyzed for each of the regulatory options separately and for the proposed regulations combined. The BPT and BAT options have no impacts on small businesses. PSES Option 2 imposes costs on relatively few small firms. However, the impacts on these firms are disproportionately large.

Limits of the Analysis

The limits of the analysis fall into two broad categories: quality of the data, both technical and economic, and methodological shortcomings and assumptions.

Section 2

Effluent Limitations and Standards

The Environmental Protection Agency is charged with the responsibility to restore and maintain the chemical, physical and biological integrity of the nation's waterways. This authority is granted under the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977). Section 301(b)(1)(A) of the Act requires that all industries discharging into navigable waterways achieve the "best practicable control technology" (BPT) by July 1, 1977. At subsequent dates, these same dischargers are required to meet effluent limitations achievable by the application of "best available technology economically achievable" (BAT) and "best conventional pollutant control technology" (BCT), pursuant to Sections 301(b)(2)(A), (b)(2)(C) and (b)(2)(E). Additionally, new industrial dischargers are required to comply with the New Sources Performance Standards (NSPS) under Section 306 of the Act, and new and existing industrial dischargers to publicly owned treatment works (POTW's) are subject to Pretreatment Standards under Sections 307(b) and 307(c) of the Act. The purpose of this study is to assess the economic impacts of such requirements on the pharmaceutical industry.

On November 17, 1976, the EPA promulgated the interim Final BPT regulations for the Pharmaceutical Industry (40 CFR 439). Under this regulation, each direct discharger of pharmaceutical manufacturing effluent was required to achieve: 90 percent removal of BOD_5 (long-term average); 74 percent removal of COD (long-term average); and a monthly maximum TSS of 52 mg/l. The technical basis of this regulation has been provided in EPA 440/1-75/060, published in December, 1976 and known as the 1976 Development Document for the Pharmaceutical Industry.

Option Descriptions*

Best Practicable Control Technology Currently Available (BPT) Effluent Limitations--Revised

- The BPT option analyzed in this study revises the existing TSS concentration limit for direct dischargers in Subcategories B,

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* A complete description of these options, along with cost estimates, is provided in Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category (EPA, September 1983), for final promulgated limitations, and Development Document for Proposed New Source Performance Standards for Control of Conventional Pollutants in the Pharmaceutical Manufacturing Point Source Category (EPA, September 1983) for proposed NSPS limitations.

D and E, and establishes a TSS concentration limit for plants in Subcategories A and C.* In addition, the discharge of cyanide is limited.

The option also adds concentration limits for BOD and COD for Subcategories B, D, and E which are alternative limits to the existing percentage removal limits for these subcategories. These alternative limits have no cost impact and will not be discussed further.

Best Conventional Pollutant Control Technology (BCT) Effluent Limitations

BCT is being addressed in a separate action; it will cover BOD_5 and TSS for direct dischargers.

Best Available Technology Economically Achievable (BAT) Effluent Limitations

- Option 1: Limit the discharge of cyanide to surface waters by direct dischargers to that set for BPT. Therefore, there would be no incremental costs associated with the cyanide limitations.
- Option 2: Limit cyanide as in Option 1 and limit the discharge of methylene chloride. This option would require steam stripping.

Pretreatment Standards for Existing Sources (PSES)

Two PSES options limiting discharge to POTW's were considered.

- Option 1: Limit the discharge of cyanide.
- Option 2: Limit cyanide as in Option 1 and limit the discharge of methylene chloride.

New Source Performance Standards (NSPS)

Two options were considered for NSPS limiting the discharge of conventional pollutants by direct dischargers.

- Option 1: BOD and TSS limits based on the use of advanced biological treatment without filtration.

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* Five subcategories have been established for the pharmaceutical industry: A = Fermentation Plants, B = Biological Extraction Plants, C = Chemical Synthesis Plants, D = Formulators, and E = Research only.

- Option 2: BOD and TSS limits based on advanced biological treatment plus filtration. The filter provides extra reduction in the level of BOD_5 and TSS.

In addition, the NSPS options include cyanide limitations equal to BPT; there are no incremental costs associated with these cyanide limitations.

Pretreatment Standards for New Sources (PSNS)

The alternatives considered are identical to the PSES options.

Section 3

Industry Profile

The pharmaceutical industry can be distinguished from most other U.S. industries by its intensive research and development efforts, aggressive marketing, higher than average profit margins, and multinational character. A high degree of involvement with regulatory agencies, notably the Food and Drug Administration (FDA), also contributes to its uniqueness. This section discusses these and other aspects of the pharmaceutical industry in order to provide the background necessary for an economic analysis of the effects of the proposed regulations on the industry. The discussion covers nine major topics and includes definition, size and cost structure of the industry, characteristics of pharmaceutical companies (such as lines of business, sales, employment) characteristics of manufacturing establishments, final products, government involvement with the industry and the influence of macroeconomic conditions. The discussion concludes with a summary of important features and trends in the industry.

Definition of the Pharmaceutical Industry

EPA defines the "Pharmaceutical Manufacturing Point Source Category" as those manufacturing establishments having any involvement in the following seven activities:

(1) Production of biological products covered by Standard Industrial Classification (SIC) Code 2831. This primarily includes blood and blood derivatives, vaccines, antitoxins, diagnostics, and other biologicals for human or veterinary use.

(2) Production of medicinals and botanicals covered by SIC Code 2833. Products classified here are synthetic organic and inorganic medicinal chemicals, as well as botanicals produced and shipped in bulk.

(3) Production of pharmaceutical preparations covered by SIC Code 2834. Most of these preparations are ready for consumption in the form of ampuls, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions. They include those for human or veterinary use.

(4) Production of products by fermentation, biological and natural extraction, chemical synthesis, and/or formulation which are considered as pharmaceutically active ingredients by the Food and Drug Administration, but which are not covered by SIC codes 2831, 2833, and 2834.

(5) Production of cosmetic preparations included in SIC Code 2844 which function primarily as skin treatments.

(6) Production of products with multiple end uses at least one of which is as a component of a pharmaceutical preparation (SIC 2834). Examples include binders, fillers, and capsules.

(7) Pharmaceutical research which includes biological, microbiological, and chemical research, product development, clinical and pilot plant activities.

Establishments conducting only pharmaceutical research would not incur costs under the options analyzed and therefore are not included in the economic analysis.

There are two large data bases containing information related to this industry. The Bureau of the Census, U.S. Census of Manufactures, defines the pharmaceutical industry in terms of three SIC groups. These are producers of biologicals (SIC 2831), medicinals and botanicals (SIC 2833), and pharmaceutical preparations (SIC 2834). These data cover 1,243 establishments in 1977.

Industry data are also available from EPA's Technical Study, acquired by an industry survey program (referred to as the 308 Survey).* Because of the need for rapid responses, EPA initially requested information from plants belonging to Pharmaceutical Manufacturers Association (PMA) member firms and non-member firms included in previous EPA guidelines work. After eliminating plants which did not manufacture pharmaceuticals as defined above, or were research-oriented facilities, or did not respond, a data base of 244 pharmaceutical manufacturing plants was obtained. Subsequently, EPA produced a revised list containing 540 additional plant sites of approximately 400 companies and distributed a supplemental 308 portfolio to these sites. From these, 220 plants were identified as pharmaceutical manufacturers and added to the original data base.**

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* A detailed description of these data gathering efforts can be found in Section II of the Development Document.

** A summary of the two 308 Surveys is as follows:

	Number	Percent of Total Sent	Percent of Total Returned
Questionnaires Sent	982		
Questionnaires Returned	786	80%	
Non-pharmaceutical/ Non-manufacturing	233		30%
Duplicates	54		7%
R&D Only	35		4%
Manufacturing	464		59%

Subsequent to the surveys, two plants were removed from the data base (because production of pharmaceuticals had closed) and four new plants were added based on information volunteered by two companies. Thus, an adjusted data base of 466 plants resulted from the 308 Survey.

Both the U.S. Census and the 308 Survey have shortcomings as data bases for analyzing these proposed regulations. The Census does not provide separate data on facilities covered by the regulations but not included in the three SIC groups considered. In addition, there is not a one-to-one correspondence between establishments as defined by the Census and by the 308 Survey. A facility may be counted as a single establishment by one and as multiple establishments by the other.* Therefore, an exact match in terms of numbers of plants is not expected. However, the sizeable disperity between the Census data (1,243 establishments) and the 308 Survey (466 plants) suggests that the 308 Survey missed some of the manufacturing plants. The 308 Survey does cover a great majority of the production of pharmaceutical products and it does include manufacturing sites not covered by these three SIC groups. The establishments not covered by the 308 Survey tend to be small. Based on the results of the 308 Survey, small facilities are much more likely to be zero dischargers. Therefore, the 308 Survey covers most of the wastewater flow from pharmaceutical manufacturing. Due to availability of information, the Census is used as the basis for most of the discussion of this chapter. However, the Census does not include much of the information on the companies owning pharmaceutical plants. Therefore, the company descriptions are based on the 308 Survey.

Industry Size and Cost Structure

The following subsection presents discussions of industry size and cost structure based on data provided by the U.S. Bureau of the Census.

Size

Table 3-1 presents data available from the 1977 U.S. Census of Manufactures for the industry. It categorizes establishments into producing pharmaceuticals according to their primary product classifications (not necessarily pharmaceuticals) and then presents various measures of size--number of establishments, number of employees, value added, and value of product shipments.

Number of Establishments. The table shows that 310 pharmaceuticals establishments produce biologicals, 177 produce medicinals and botanicals, and 756 produce pharmaceutical preparations as their primary product.

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* There is a similar problem when sales data from Economic Information Systems (EIS) are matched to 308 or Census data.

Table 3-1.

Summary of Selected Measures of Size for the Pharmaceutical Industry

	Pharmaceutical Establishments Whose Production is Greater than 75 Percent in the Following SIC:				
	SIC 2831 Biological Products	SIC 2833 Medicinals/ Botanicals	SIC 2834 Pharmaceutical Preparations	All Other SICs 1/	Total for All Pharmaceutical Establishments
Number of establishments	310	177	756	na	na
All employees (1000's)	15.7	14.4	126.4	na	na
Production employees (1000's)	8.8	8.4	63.1	na	na
Value added (mm$)	563	1,162	8,214	na	na
Value of Product Shipments for (mm$):					
1) Biologicals (SIC 2831)	781	2/	244	2/	1,068
2) Medicinals and botanicals (SIC 2833)	10	1,500	384	312	2,206
3) Pharmaceutical Preparations (SIC 2834)	20	64	9,363	193	9,640
4-7) Other products and activities in the Industry Definition[1]	na	na	na	na	na
Production and miscellaneous receipts not in the Industry Definition	na	na	na	na	na
All products	898	1,890	11,460	na	na

1/ See Definition of the Pharmaceutical Industry, presented earlier in this section.

2/ Withheld by the Census of Manufactures to avoid disclosure of individual operations.

na = not available

Source: Census of Manufactures (1977)

These 1,243 establishments produce 96 percent of the three types of products. The number of facilities producing the remaining four percent is unknown.

Number of Employees. As shown in Table 3-1, these 1,243 pharmaceutical establishments employed 156.5 thousand persons, with a little more than half, or 80.3 thousand, directly involved in production. The majority of these were employed in establishments classified in pharmaceutical preparations (SIC Code 2834). However, because some of the production at these establishments is not pharmaceutically related and no estimate has been made of pharmaceutical employment at establishments in non-pharmaceutical SICs, these employment figures may not accurately indicate pharmaceutical employment.

Value Added and Value of Shipments. Value added and value of shipments are measures of the size of an industry. Value added is derived by subtracting the cost of inputs including contract work from the value of shipments (products manufactured plus receipts for services rendered). In 1977, value added for establishments in the three SICs totaled $9.9 billion with the majority ($8.2 billion) in pharmaceutical preparations (see Table 3-1). Value of shipments for each SIC group was $0.9, $1.9, and $11.5 billion for establishments in SICs 2831, 2833, and 2834, respectively. The value of shipments of pharmaceutical products was approximately $12.1 billion in 1977 (the value of shipments classified under SIC 283 less intra-industry shipments of $0.8 billion). Compared to the 1977 gross national product of $1.9 trillion, the pharmaceutical industry contributed at least one half of one percent to national output.

Cost Structure

Revenues from pharmaceutical product sales can be broken into several categories of expenditures: research and development (R&D), cost of goods sold, marketing costs, general and administrative expenses (G&A), and net income before taxes. Different researchers assign different percentages to each of these categories.

According to one marketing service,* the proportional breakdown of expenditures is: cost of goods sold (30 percent); marketing (35 percent); R&D (12 percent); G&A (3 percent); and net income before taxes (20 percent). Included in the cost of goods sold is the cost of purchased materials (such as energy, chemicals, plant and animal matter, binders and fillers) and wages.

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* Delphi Marketing Services, Inc., Outlook for the Pharmaceutical Industry to 1985.

The Federal Trade Commission's Line of Business Report for 1976 presents somewhat different estimates. The report presents data separately for ethical and proprietary pharmaceuticals* (see Table 3-2). However, the following are averages for both segments. As a ratio to sales: cost of goods sold, (44.6 percent); marketing (23.5 percent); R&D (8.3 percent); other G&A (8 percent); operating income (15.6 percent). The FTC quarterly reports indicate that operating income is approximately the same as income before taxes (because non-operating income and expenses,e.g., for interest, balance out).** These income figures exclude foreign earnings.

The FTC Line of Business data indicate some marked differences between the ethical and proprietary segments. Marketing expenses are much higher for proprietary drugs (33.7 percent of sales vs. 20.6 percent for ethical) primarily due to much higher media advertising expense (19.1 percent of sales vs. 4.2 percent for ethical). There is also a marked difference in R&D expense: 10.0 percent for ethical and 2.4 percent for proprietary.

The FTC quarterly report also gives profit rates for major industrial groups. In 1980, pharmaceutical after-tax profits were 11.3 percent of sales. This was 1.79 times the after-tax profit rate for all chemical and allied industries, and 2.35 times the after-tax profit rate for all manufacturing industries.

Research and Development. R&D is more important to the pharmaceutical industry than it is to most industries. Ethical drugs ranked number one in terms of the ratio of R&D to sales, and proprietary drugs ranked 39 out of 234. Its role in improving existing products and creating new ones has enabled pharmaceutical companies to continue to earn above average profits. This is especially true for competitors in ethical drug markets.

R&D expenditures fall into two categories: 1) research for the advancement of scientific knowledge and development of new products and related services; and 2) research oriented to improvement and/or modification of existing products. In 1977, members of the Pharmaceutical Manufacturers Association (PMA) spent 80 percent of total R&D expenditures on new products, and 20 percent on improvements in existing products.*** In 1979, PMA member firms spent $1,330 million on domestic R&D for ethical drugs (both new products, and product improvement), with an additional $300 million of company financed R&D performed outside of the United States. For these PMA member firms, this represented 8.3 percent of their 1979 worldwide human and veterinary ethical drug sales.

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* Ethical drugs are those which require prescriptions, proprietary do not.

** Quarterly Financial Report for Manufacturing Mining and Trade Corporations, 1980 q4, U.S. Federal Trade Commission.

*** According to the 1980 edition of The Kline Guide to the Chemical Industry, PMA member firms account for 95 percent of all domestic sales of prescription drugs.

Table 3-2. Operating Ratios, Based on 1976
Line of Business Data *

	Operating Income to Sales (Percent)	Media Advertising to Sales (Percent)	Total Selling Expense to Sales (Percent)	Total R&D to Sales (Percent)	G & A** to Sales (Percent)
Ethical Drugs	15.8	4.2	20.6	10.0	7.7
Proprietary Drugs	14.9	19.1	33.7	2.4	9.1

* Annual Line of Business Report: 1976 (Interim), Statistical Report of the Bureau of Economics to the Federal Trade Commission, May 1982.

** Excluding R&D.

These R&D expenditures are spread unevenly among product classes, ranging from 0.4 percent for veterinary biologicals to 16.8 percent for pharmaceutical preparations acting on the central nervous system and sense organs (see Table 3-3*). The ratio of ethical R&D expenditure to the value of ethical product shipments is another measure of the relative emphasis placed on R&D for each product class. These values range from 3.1 percent in vitamins, nutrient and hematinic preparations to 26.2 percent for pharmaceutical preparations for veterinary use, one of the smaller groups. A small percentage tends to be characteristic of a mature product class where continual innovation is difficult or unlikely to enhance a firm's market position. Conversely, a larger percentage might be indicative of intense competition to maintain market shares through innovation or a reasonable potential for breakthroughs into new markets. Biogenetic research is an example of this second case.

Capital Expenditures and Production Labor. Available data indicate that the Pharmaceutical Industry is not particularly capital intensive, as measured in terms of new capital expenditures. In 1977, for establishments classified in SICs 2831, 2833, and 2834, capital expenditures equaled less than six percent of value added (see Table 3-4). In contrast, the Chemical and Allied Products industry is much more capital intensive with capital expenditures of 15 percent of value added. Production labor for the three categories account for ten percent of value added (see Table 3-4) varying from 9.5 percent in pharmaceutical preparations (2834) to 16.1 percent for biologicals (2831).

Table 3-4. Capital Expenditures and Labor Cost for Pharmaceutical Establishments by SIC Groups in 1977

Establishments Classified in:	New Capital Expenditures (mm$)	Prod Work Wages (mm$)	As a Percent of Value Added	
			Capital Expenditures	Labor Costs
SIC 2831	35.6	90.5	6.3 percent	16.1 percent
SIC 2833	125.1	127.2	10.8	10.9
SIC 2834	424.1	799.4	5.2	9.5
Total	584.8	997.1	5.9	10.0

Source: 1977 U.S Census of Manufactures.

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* Data for 1977 is the latest year for U.S Census of Manufactures data on which the product breakdown is based. Since the U.S Census of Manufactures covers shipments of domestic establishments only, the U.S. R&D figures are presented rather than global. A global comparison is preferred because R&D benefits and sales cross national boundaries.

Table 3-3. Absolute and Relative Distribution of the U.S. R&D Dollar for Ethical Pharmaceuticals in 1977

SIC Code[2]	Product Class	Millions of Dollars		Product R&D as a Percent of Total R&D	R&D as a Percent of Ethical Drug Shipments
		Value of Ethical Drug Product Shipments	Domestic R&D		
28311	Biological Products for human use	na			na
28312		na	33	3.1	na
28313		na			na
28314	Biological Diagnostics (in vivo) for human use	na	12	1.1	na
28315	Biological Products for veterinary use	na	4	0.4	na
28316	Biological Products for industrial use	na	[1]	[1]	na
28310	Biological Products not specified by kind	na	[1]	[1]	na
28341	(p.p.h.u.) affecting neoplasms, the endocrine system and metabolic diseases	879.5	165	15.7	18.8
28342	(p.p.h.u.) acting on the central nervous system and the sense organs	1675.3	177	16.8	10.6
28343	(p.p.h.u.) acting on the cardiovascular system	745.1	160	15.2	21.5
28344	(p.p.h.u.) acting on the respiratory system	486.8	44	4.2	9.0
28345	(p.p.h.u.) acting on the digestive or genito-urinary systems	725.5	65	6.2	9.0
28346	(p.p.h.u.) acting on the skin	229.8	35	3.3	15.2
28347	Vitamins, nutrient and hematinic preparations for human use	782.9	24	2.3	3.1
28348	(p.p.h.u.) affecting parasitc and infective disease	1092.9	196	18.6	17.9
28349	pharmaceutical preparation for veterinary use	248.2	65	6.2	26.2
28340	Pharmaceutical preparations not specified by kind	na	[1]	[1]	na

(p.p.h.u.) = pharmaceutical preparations for human use.

na = not available

[1] R&D for SIC Codes 28316, 28310, and 28340 totals $73 million and represents 6.9 percent of total R&D.

[2] SIC 2833 is not included because it includes only bulk medicinals and botanicals.

Source: Census of Manufactures; 1977-78 PMA Annual Survey; and Meta Systems calculations.

These 1977 figures are only somewhat typical for the industry. Comparing these ratios over time (1963, 1967, 1972 and 1977), labor as a percent of value added has fallen in SICs 2831 and 2833, while it has returned to its earlier level in SIC 2834. New capital expenditures as a percent of value added declined steadily throughout the period for SIC 2831, had increased steadily between 1963 and 1972 and then returned to near the 1963 level in 1977 for SIC 2833, and reached its highest level in 1977 for SIC 2834.

Marketing. Two distinct advertising and marketing approaches are employed by pharmaceutical companies. The first strategy pertains to sales* of proprietary drugs--drugs which do not require prescriptions and are marketed directly to consumers. Media advertising--television, radio, newspapers, magazines, and billboards--are the primary means of promoting these products with the general strategy being similar to that for most consumer products.

The second strategy pertains to the sales of ethical products. Since these drugs require prescriptions, the advertising and marketing strategy for ethical products is aimed towards doctors. Advertisements in professional journals and magazines are used to achieve visibility of a product or product line. In addition, a "detail" sales force visits individual doctors frequently to make a personal sales pitch. Depending on the company and its product line, the detail force can be substantial in size.

The dichotomy in marketing strategies is beginning to blur. Some companies have begun to aim ethical drug ads directly at consumers in the hope that a more aware consumer may influence doctors' prescription habits.

Pharmaceutical Companies

The U.S. Bureau of the Census provides detailed information on individual establishments but only limited information on the individual companies which manufacture pharmaceuticals. Therefore, the following discussion of company characteristics focuses on the companies covered in the

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* Based on a breakdown of pharmaceutical preparations (SIC 2834) value of shipments, approximately 73 percent are ethical, 25 percent are proprietary, with the remaining two percent being bulk shipments (1977 U.S Census of Manufactures).

308 Survey. This data base consists of 466 establishments owned by 242 companies.* Based on a comparison of the 308 Survey data with the Census data, the 308 data contains a larger proportion of large companies and large establishments. In the following discussions, the companies in the 308 Survey are characterized in terms of sales and employment, concentration, integration, lines of business and ownership.

Sales and Employment

While the majority of companies associated with the pharmaceutical industry tend to be small, the major portion of pharmaceutical sales are attributable to a relatively small number of large, integrated firms (such as Johnson & Johnson, Lilly, Abbott and Baxter-Travenol). Many large, diversified firms also have pharmaceutical operations (General Electric, Shell, DuPont, Tenneco and Dow). The distribution of sales and employment for all 242 companies in the 308 survey for both their pharmaceutical and non-pharmaceutical operations is shown in Table 3-5. Mean employment was 10,500 and mean annual sales was $1.0 billion. Data are unavailable for some small privately held companies, causing these figures to be slight overestimates.

Table 3-5. Company Employment and Sales Distributions for the "308" Survey Companies

Employment		Sales	
Employees	Number of Companies	Sales (mm$)	Number of Companies
0 - 100	97	0 - 10	95
100 - 1,000	42	10 - 100	34
1,000 - 10,000	37	100 - 1,000	33
10,000 - 100,000	43	1,000 - 10,000	42
More than 100,000	4	More than 10,000	5
Missing employment data	19	Missing sales data	33
Total	242	Total	242

Source: 10-K and Annual Reports (Fiscal 1980), Dun and Bradstreet, State Industrial Guides.

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* The 1977 U.S. Census of Manufactures identifies 249 companies in SIC 2831, 154 in SIC 2833, and 655 in SIC 2834. No information is provided regarding how many companies have establishments in more than one of these SIC groups. Therefore, the total number of firms with establishments in these three SIC groups could range from 655 to 1058. As discussed earlier, some establishments (and therefore some firms) in these SIC groups may not be covered by these proposed regulations. In addition, the 308 Survey included some establishments covered by the regulation which may not fall in these three SIC groups.

Since the total employment and sales for the firms represented in Table 3-5 are many times the figures for pharmaceutical employment and sales alone, an additional tabulation was run from the 308 Survey data aggregating plant employment and sales by company. For the 242 companies, the sales of their establishments producing pharmaceuticals was $19.9 billion and the employment as reported in the 308 Survey was 113,600, implying mean company pharmaceutical sales of $82 million and mean company pharmaceutical employment of 470. The median company sales of pharmaceuticals was $10 million, and ranged up to the four integrated companies mentioned above with sales of $1-2 billion. Median company employment was 100, ranging to over 2,500 persons for 14 companies.

Concentration

The degree to which sales are concentrated in a few companies is often measured by the four-firm and eight-firm concentration ratios. A high ratio indicates that a few firms control a large segment of the market, and this may result in less competition. As shown in Table 3-6, this industry is quite concentrated for SIC 2831 and 2833. Pharmaceutical preparations (SIC 2834) is much less concentrated. The U.S Census of Manufactures also publishes concentration ratios for each SIC group. In all cases, the concentration ratios based on the 308 Survey are higher than those provided by the Census. In part this is due to the Census including a higher proportion of smaller firms than does the 308 Survey. The concentration of firms manufacturing pharmaceutical preparations (SIC 2834) has remained relatively constant since at least 1947 in spite of a trend in the pharmaceutical industry toward larger companies.*

Table 3-6. Concentration Ratios for Firms Operating Pharmaceutical Establishments, by SIC Classification

SIC Group	Percent of Total Sales Attributable to	
	Four Largest Firms	Eight Largest Firms
2831	63	83
2833	62	85
2834	28	48

Source: 308 Survey and Meta Systems' calculations.

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* Peter Temin, "Technology, Regulation, and Market Structure in the Modern Pharmaceutical Market," Bell Journal of Economics, Autumn 1979, Vol. 10(2).

These concentration ratios are based on total sales rather than pharmaceutical sales alone. However, since the specialization ratios are high in SICs 2831, 2833, and 2834, it is reasonably certain that these concentration ratios apply to pharmaceutical sales as well. (See discussion of specialization under "Pharmaceutical Establishments".)

Integration

Before 1950, few pharmaceutical companies were integrated from research and development through formulation and marketing. With the maturing of research and development, new markets developed and competition between similar patented products became more common. Company level integration increased markedly during the 1960's.* Today, the industry is characterized by large integrated pharmaceutical and cosmetics companies, large chemical companies that are not integrated along pharmaceutical lines and smaller, less integrated companies. Virtually all of the large pharmaceutical firms are integrated from R&D to marketing, and these large firms dominate R&D in the industry.

The 308 Survey provides data on the production processes employed by each firm. Dividing these up into two categories: (1) bulk manufacturing by chemical synthesis, fermentation, or biological extraction, and 2) formulation, a partial measure of integration is possible, (see Table 3-7). It is only partial because the R&D segment of the industry has been ignored. By this measure 28.5 percent of the companies are integrated from manufacturing to formulation, while the majority (59.1 percent) only formulate.

Table 3-7. A Measure of Company Integration in the 308 Sample

Activity	Number of Companies*	Percent of Total
Chemical synthesis, fermentation, and/or extraction only	30	12.4
Formulation only	143	59.1
Both	69	28.5
Total	242	100.0

* Two companies lacked production data.

Source: 308 Survey and Meta Systems' calculations.

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* Peter Temin, op. cit..

Lines of Business

Although most companies involved in pharmaceutical activities are principally pharmaceutical companies, some non-pharmaceutical companies are also involved. The latter situation usually occurs when the pharmaceutical production is a by-product of another major line of business. Examples are: chemical companies which also produce medicinal chemicals, such as Tenneco, Inc.'s production of salicylic acid; and a consumer products company, such as General Foods which produces medicinal caffeine for use in cold remedies.

Of the 242 companies in the 308 sample, 212 are classified by Dun and Bradstreet according to their principal activity. Nearly two-thirds or 141 are principally active in SIC codes 2831, 2833, or 2834. Most of these companies (123) are associated with SIC 2834. SICs 2831 and 2833 were assigned to 4 and 14 companies, respectively. Outside of these three SIC groups, the largest concentration of companies is found in SIC groups 281 (industrial inorganic chemicals), 284 (soap, detergents, perfumes, cosmetics and other toilet preparations), 286 (industrial organic chemicals) and 384 (surgical, medical and dental instruments and supplies).

Ownership

Public companies tend to be larger than private ones in most U.S. industries.* The pharmaceutical industry follows this pattern. Table 3-8 indicates the number of pharmaceutical establishments owned by each firm in the 308 data base. The 92 public companies own 279 pharmaceutical establishments and the 150 private firms own only 185 pharmaceutical establishments.

Table 3-8. Number of Pharmaceutical Establishments
Reported by Private Versus Public Companies

	Number of Pharmaceutical Establishments Owned			
Ownership	One	Two	Three or Four	Five or Greater
Public 92 firms	49	10	10	23
Private 150 firms	138	5	5	2
Total 242 firms	187	15	15	25

Source: 308 Survey and Meta Systems' Calculations.

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* The term "public company" is defined as a company required to file 10K reports with the SEC. This definition may exclude foreign public companies with U.S. operations from the public category.

During the past decade, foreign ownership has become an important characteristic of pharmaceutical companies manufacturing in the United States. Table 3-9 shows the ownership status of the 242 companies in the 308 data base, with 24 out of 242 companies having more than ten percent foreign ownership. One third of these represent foreign holdings of stock available in the U.S. The remaining two-thirds are firms which do not file 10Ks and therefore are privately owned, publicly owned with no stock for sale in the United States, or owned by a foreign government.

Table 3-9. Extent of Foreign Ownership
in Domestic Pharmaceutical Companies

Percent Foreign Ownership	Publicly Held	Privately Held	All
Greater than 10 percent	8	16	24
Less than or equal to 10 percent	85	134	218
All	93	150	242

Source: 308 Survey, Economic Information Systems and 10-K Reports.

Establishment Characteristics

The following discussion is based on data from the U.S. Census of Manufactures. Establishments are characterized in terms of sales and employment, geographic distribution, specialization and age.

Sales and Employment

The employment distribution across establishments is presented in Table 3-10. Over one-half of the establishments have fewer than twenty employees.

Table 3-10. Establishment Employment Distributions, for Establishments in SIC Codes 2831, 2833 and 2834

Number of Employees	Number of Establishments by SIC Group 2831	2833	2834	Total Number of Establishments	Percent of Total Establishments
1- 4	108	42	299	449	36
5- 19	89	59	164	312	25
20- 99	74	53	135	262	21
100- 499	34	17	100	151	12
500-2499	5	5	49	59	5
More than 2499	0	1	49	10	1
Total	310	177	756	1,243	100

Source: U.S. Census of Manufactures (1977).

Average annual sales and employment have been calculated for each of the three SIC classes (see Table 3-11). SIC 2834 establishments tend to be larger and SIC 2831 establishments tend to be smaller than the average pharmaceutical establishment.

Table 3-11. Average Establishment Sales and Employment

	Sales (mm$)	Employment
SIC 2831	2.9	51
SIC 2833	10.7	81
SIC 2834	15.2	167
Mean for the three SIC groups	11.5	126

Source: U.S. Census of Manufactures (1977).

Geographical Distribution

According to the U.S Census of Manufactures, 41 percent of all pharmaceutical establishments are located in New York, Illinois, and California. The Census does not report on plants located in Puerto Rico. However, another source reports 76 drug and pharmaceutical establishments in Puerto Rico in 1979, giving it the fourth largest concentration.*

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* The Drug and Pharmaceutical Industry in Puerto Rico, June 1980, Puerto Rico Economic Development Administration, p. 2.

Specialization

The specialization ratio is defined here as the ratio of the value of product shipments for products included in the industry definition (i.e., sum of products in SIC 2831, 2833 and 2834) divided by the total value of product shipments at the establishment (see Table 3-12.).* These ratios demonstrate that pharmaceutical establishments are highly specialized.

Another measure of specialization provided by the U.S Census of Manufactures shows that of the 310 establishments in 2831, 294 (94.8 percent) have greater than 75 percent of their production within that SIC group. Likewise, 90.4 percent and 90.3 percent of the establishments in SICs 2833 and 2834 have at least 75 percent of their production falling in their primary SIC.

Age

The establishment age distribution is illustrative of industry capital improvement trends. The U.S Census of Manufactures does not provide this information, but data on the start-up year was provided for 232 of the 464 establishments in the 308 Survey. According to this data a disproportionately large number of older plants exist in the upper Midwest, while the newer plants are disproportionately concentrated in Puerto Rico, the location of 26 of the 73 establishments which opened between 1970 and 1977.

Final Product Groups

For the purposes of the economic analysis, final pharmaceutical products are grouped into eleven major classes following the U.S. Census Bureau classification scheme. The nine major groups from SIC code 2834 (Pharmaceutical Preparations) and two groups from SIC 2831 were selected. SIC code 2833 (medicinals and botanicals) was not included because almost all products within it are feedstocks to SIC 2834 finished products. The eleven major groups are**:

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* The U.S. Census of Manufactures defines specialization in a slightly different way. It is the ratio of products in the plant's own SIC group only divided by the total shipments of that plant. The Census specialization ratios are slightly less than the ones calculated by Meta Systems, but still show a highly specialized industry.

** A more complete discussion of each of these groups, including important subgroups within each major group and their market characteristics can be found in Appendix B.

Table 3-12. Specialization Ratios Based on Total Pharmaceutical Production; for Pharmaceutical Establishments in Each SIC Group

Establishments Classified in SIC	Minimum Specialization Ratio (Percent)
2831	96
2833	86
2834	92

Source: Calculated from Table 3-1.

1. Preparations affecting neoplasms, endocrine system and metabolic diseases.
2. Preparations affecting the central nervous system and sense organs.
3. Preparations acting on the cardiovascular system.
4. Preparations acting on the respiratory system.
5. Preparations acting on the digestive and genito-urinary systems.
6. Preparations acting on the skin.
7. Vitamins, nutrients and hematinic preparations.
8. Preparations affecting parasitic and infective diseases.
9. Preparations for veterinary use.
10. Blood and derivatives for human use.
11. Preparations for active and passive immunization and therapeutic counterparts.

Since the Second World War, the pharmaceutical industry has grown at a rate much greater than the average for all industries. Table 3-13 shows the value of shipments and percent annual change for the major product groups from 1972 to 1977. Value of shipments growth following 1974 had a much larger inflationary component than growth prior to that year. Consequently, it is difficult to determine "real" growth from this table.

Table 3-14 divides each product class into its ethical and proprietary components. Ethical drugs, those promoted primarily to the medical professions, comprise approximately 73 percent of the total value of shipments of final products (SIC 2834).* Although most pharmaceutical com

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* This percentage varies across product classes. Ethical drugs as a percent of total value of shipments ranges from 37 percent for preparations acting on the skin to 99 percent for preparations affecting the cardiovascular system.

Table 3-13. Pharmaceutical Final Product Class Value of Shipments (current dollars)

Product Class	Value of Shipments (mm$) 1977	Value of Shipments (mm$) 1972	Average Rate of Growth (Percent)
Preparations affecting neoplasms, endocrine system and metabolic diseases	900	615	7.9
Preparations affecting central nervous system and sense organs	2231	1636	6.4
Preparations affecting cardiovascular system	751	400	13.4
Preparations affecting respiratory system	896	561	9.8
Preparations affecting digestive and genito-urinary systems	1074	746	7.6
Preparations affecting the skin	621	344	12.5
Vitamins, nutrients and hematinics	1302	587	17.3
Preparations affecting parasitic and infectious diseases	1285	948	6.3
Preparations for veterinary use	354	214	10.6
Blood and blood derivatives for human use	243	126	14.1
Active and passive immunization agents and therapeutic counterparts	126	89	7.2
Total	9783	6266	9.3

Source: 1977 U.S Census of Manufactures Report (Current Industrial Reports figures).

Table 3-14. Breakdown of Final Product Classes Into Ethical and Proprietary Drug Categories (1977)

Product Class	Value of Shipments (mm$)				Value of Ethical Shipments as a Percent of Total
	Ethical	Proprietary	Bulk+	Total@	
Preparation affecting neoplasms, the endocrine system, and metabolic diseases	880	*	20	900	97.8
Preparations affecting the central nervous system and sense organs	1675	538	17	2231	75.1
Preparations affecting the cardiovascular system	745	*	6	751	99.3
Preparations affecting the respiratory system	477	412	7	896	53.2
Preparations affecting digestive and genito-urinary systems	726	336	12	1074	67.5
Preparations affecting the skin	230	378	13	621	37.0
Vitamins, nutrients, and hematinics	783	382	137	1302	60.0
Preparations affecting parasitic and infectious diseases	1093	176	16	1285	85.1
Preparations for veterinary use	248	94	11	354	70.1
Total	6857	2316	239	9414	72.8

+ Preparations shipped in bulk, not considered as ethical or proprietary.

* Not applicable.

@ Some totals may not equal the sum of the parts due to rounding.

panies produce both ethical and proprietary drugs, the distinction is important for discussing the market characteristics, namely volume growth and price trends, of each product class. Research and patents tend to be more important in the ethical drug markets. In addition, profits in these markets tend to be higher. These factors, combined with marketing differences (targeting the medical professions versus consumers) make the ethical/proprietary distinction a relevant one.

Government Involvement

Regulation to protect the consumer is one of the most important ways the Federal Government influences the pharmaceutical industry. In addition, there are Federal regulations governing patent and trademark systems and Federal tax incentives which influence industry activities.

Consumer Regulation

The Food and Drug Act of 1906 set up minimum standards of strength, quality, and purity for drugs marketed in interstate commerce.* The first major revision was the Food, Drug, and Cosmetic Act of 1938 which emphasized safety by requiring that any new drug not generally recognized as safe be shown to be so prior to marketing. Today, drugs also have to be demonstrated as effective, as required by 1962 amendments to the Food, Drug, and Cosmetics Act.

The development of a safe and effective drug and the associated regulatory requirements can be characterized in three basic steps. The first is the establishment and investigation of a chemical formulation with a potential for use as a pharmaceutical. This includes testing of the compound's chemical and toxicological properties. Second, if the compound is promising, further testing is done including the use of animal subjects. If the prognosis is still favorable, an Investigational New Drug (IND) application is filed with the FDA to obtain permission to test the drug on humans. If approved, the third step is clinical testing on human subjects--first on healthy volunteers, then on those suffering from the symptoms or disease to be treated by the drug. After completion of the clinical tests, a New Drug Application (NDA) is filed with the FDA. If approved, the drug can be marketed.

Due to the long process, the tremendous cost involved, and the significant attrition rate of potential new drugs, R&D has increasingly focused on the potentially lucrative therapeutic markets--health areas such as cancer and heart disease--where a successful drug could create a sizable market and earn significant profits.

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* In effect this includes all drugs. The interstate commerce clause of the Constitution is often cited as the authority for Federal regulation.

There is growing concern that these regulations are stifling innovation and thus, reducing the number of important new drugs developed. The relationship is not a simple one. However, steps are being taken to reduce the time involved in the FDA approval process.

Another area of Federal consumer regulations involves generic drugs. The Court of Appeals for the 8th Circuit has upheld the FDA's contention that a generic copy of an approved drug with the same active ingredients must be submitted for approval since the inactive ingredients may alter the safety and/or effectiveness of the product.* The generic drug companies do not want to incur the time and expense of this approval process.

Patents and Trademarks

Under the current Patent Act, a patent provides its holder with 17 years of exclusive rights to an innovation. Patents may cover new compositions of matter, as well as new processes or new uses for an old substance (the latter possibility was added with the 1952 Amendment).

Opinions concerning the merits of patents in the pharmaceutical industry vary significantly. On the positive side is the incentive for innovation supplied by the patent. Seventeen years of exclusive rights to a drug formulation can be quite profitable and is often necessary to pay off the resource-intensive investment in the development and approval of a new drug, with society benefitting from the proliferation of new products. On the negative side, patents are sometimes viewed as a barrier to entry. New companies are allowed to produce, subject to FDA approval, any of the many drugs not covered by patents; however, these tend to be less profitable. The other major drawback is the tendency of drug companies to apply for peripheral patents of closely related compounds, thus protecting the main application from imitation by competitors. This barrage of patent applications may dissuade other companies from doing research closely related to a recent discovery.

The Patent Term Restoration Act now pending in Congress is renewing interest in the topic. If passed, it will provide an extension of up to seven years of patents for products (including, but not limited to pharmaceuticals) which have lost part of their patent life in the regulatory approval process. At least part of the motivation behind the proposal springs from the contention that the regulatory process is becoming more and more time-consuming and burdensome, thereby reducing the incentive for innovation.

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* United States v. Undetermined Quantities of Various Articles of the Drug Equidantin, 675 F.2d 994 (8th Cir. 1982).

Trademarks are another means of protecting markets. In Inwood v. Ives, 50 U.S.L.W. 4592 (June 1982) the Supreme Court recently recognized the latitude generic manufacturers have in designing their products to look like original brand names.

Tax Incentives

The Federal government also influences the pharmaceutical industry through the enactment of tax incentives. Two incentives are of particular interest: the incentive to attract investment to Puerto Rico and a recent provision to stimulate R&D investment. Many of the larger pharmaceutical companies have established subsidiaries in Puerto Rico to take advantage of Federal and local income tax exemption policies. However, these benefits have been reduced by recent tax legislation. This will result in reduced profitability for plants located in Puerta Rico.

Recent action has also been taken to spur R&D investment. The Economic Recovery Tax Act of 1981 included a provision allowing all companies a 25 percent tax credit on R&D expenditures which represented an increase over average expenditures during a base period.* The credit went into effect July 1, 1981, and will continue through the end of 1985. It is too early to assess its effectiveness in achieving its goal.

Other Involvement

The pharmaceutical industry is affected in a more indirect way by such programs as Medicare and Medicaid and state generic substitution laws. In response to the rising cost of national health care programs a Maximum Allowable Cost (MAC) program was initiated in August 1976. The objective was to lower the costs of these programs by setting maximum prices for drugs dispersed under Medicare and Medicaid. Since generics are generally lower priced this type of action often benefits generic drugs at the expense of brand name drugs.

In a separate effort, state generic drug substitution laws--such as the one in New York--keep the cost of drugs down by requiring pharmacists to substitute generic equivalents in prescriptions except when the physician specifically requires a name brand. This also favors generic drugs.

Foreign Trade

Pharmaceuticals compete in an international marketplace in which the United States is the largest national participant. We are the largest producer, largest consumer (with 16 percent of worldwide sales in 1975), largest developer of ethical drugs (with 24 percent of all new drugs between 1961 and 1973) and second largest exporter of pharmaceuticals.

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* In the first year the base period is the previous year. It is the previous two years in the second and the previous three years for each succeeding year of the credit.

In 1977, the U.S. was second only to West Germany in the sales volume of its pharmaceutical exports and second to Switzerland in net exports (i.e., exports minus imports). In that year, the three industry SIC groups had exports amounting to $1.22 billion, representing nine percent of the total value of shipments for that year of $13.6 billion. Table 3-15 presents the exports by SIC group, over the period of 1977 to 1980. Since many countries have tariffs or other barriers which serve to discourage the import of prepared pharmaceuticals (to encourage local manufacturing activity), most U.S. exports are ingredients and intermediate products to be formulated and packaged abroad. Table 3-16 gives the value of imports for the years 1977 through 1980. Exports have exceeded imports by more than 85 percent in each of the four years. The largest class of imported products was bulk antibiotics (part of bulk medicinals and botanicals) constituting 13 percent of all imports in 1980. Another export characteristic is the large number of pharmaceuticals that are not marketed in the United States.* In some instances the market potential for the product may be too limited (such as drugs for tropical diseases) and in other cases the approval process for sale in the U.S. has not been completed.

Most U.S. exports are sent to western Europe, with lesser amounts sent to Japan and Latin America (see Table 3-17). As with exports, most of our imports come from Western Europe (see Table 3-18). Japanese imports have been growing and are expected to increase significantly over the next several years.

Over 40 U.S. companies operate branches or subsidiaries abroad to manufacture and package products for local distribution. Many of these products have no U.S. market. In 1977, the total sales volume of U.S. subsidiaries was $4.9 billion. This volume has been growing rapidly over the past decade (more rapidly than domestic sales) and is expected to continue in the near future. Several foreign corporations have established operations in the U.S. A 1976 Commerce Department survey reported that these subsidiaries tallied U.S. sales exceeding $1.3 billion (about ten percent of U.S. consumption). In addition, many more U.S. companies are owned in part by foreign interests. (As shown in Table 3-9, roughly 10 percent of the companies on the 308 Survey have greater than 10 percent ownership by foreign interests.)

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* According to a 1976 report by Delphi Marketing Services Inc., three out of every four specific drugs synthesized in the U.S. are not marketed here.

Table 3-15. Value of U.S. Pharmaceutical Exports
(Millions of current dollars)

Year	Total Pharmaceuticals	SIC 2831 Biologicals	SIC 2833 Medicinals/ Botanicals	SIC 2834 Pharmaceutical Preparations
1977	1463.1	138.5	1024.7	299.9
1978	1446.7	187.4	924.1	335.2
1979	1634.1	295.5	999.2	339.4
1980	1966.0	387.5	1157.4	421.1

Source: U.S. Department of Commerce

Table 3-16. Value of U.S. Pharmaceutical Imports
(Millions of current dollars)

Year	Total Pharmaceuticals	SIC 2831 Biologicals	SIC 2833 Medicinals/ Botanicals	SIC 2834 Pharmaceutical Preparations
1977	597.2	7.1	556.1	34.0
1978	781.1	9.2	722.2	49.7
1979	810.2	9.0	744.5	56.7
1980	903.4	15.3	826.5	61.6

Source: U.S. Department of Commerce

Table 3-17. World Distribution of U.S. Exports in 1980

	Export Value (mm $)						
SIC Class	Canada	Latin America	Western Europe	Japan	Other Asia	Other World	Total
Biologicals (2831)	23.3	38.7	200.2	99.4	15.2	10.6	387.5
Medicinals and Botanicals (2833)	69.6	173.1	604.5	160.9	71.0	78.3	1157.4
Pharmaceutical Preparation (2834)	49.8	61.1	109.0	80.0	76.9	44.2	421.1
Total	142.7	272.9	913.7	340.3	163.1	133.1	1966.0

Source: U.S. Department of Commerce

Table 3-18. World Distribution of U.S. Imports in 1980

	Import Value (mm $)						
SIC Class	Canada	Latin America	Western Europe	Japan	Other Asia	Other World	Total
Biologicals (2831)	3.8	0.1	10.2	0.7	0.2	0.2	15.3
Medicinals and Botanicals (2833)	15.8	28.9	565.9	118.7	29.2	68.0	826.5
Pharmaceutical Preparation (2834)	0.9	0.4	54.4	3.3	2.4	0.2	61.6
Total	20.5	29.4	630.5	122.7	31.8	68.2	903.4

Source: U.S. Department of Commerce

Influence of Macroeconomic Conditions

Output levels in many industries are tied closely to overall industrial output, or business cycles. An econometric examination of the relationship between the industrial production levels and pharmaceutical production levels showed that while they were highly correlated, the relationship is not necessarily causal in nature.

Production levels were measured by the:

1) industrial production index (INDUSTI) to capture aggregate economic performance and thus the business cycles, and

2) pharmaceutical production index (PHARMI) to capture levels of economic performance in the pharmaceutical industry (as covered by the three-digit SIC 283 industry).

Since 1956, total industrial production has grown at an average annual rate of 3.2 percent, while pharmaceutical production has grown at an average rate of 8.1 percent. See Figure 3-1. In addition, swings in pharmaceutical production appear to coincide with overall business cycles.

To test this relationship, a regression was estimated relating the log of pharmaceutical production (LPHARMI) to the log industrial production (LINDUSTI), using the Cochrane-Orcutt procedure to correct for serial correlation. The results are:

$$\begin{aligned} \text{LPHARMI} &= -4.29 + 1.95(\text{LINDUSTI}) \\ &\quad\ (-10.52)\quad (22.10) \\ \text{R squared} &= .953 \\ \text{F ratio} &= 508.05 \end{aligned} \tag{1}$$

t-statistics in parentheses

These results indicate a strong relationship between the two producion indices and explain a great deal of the variation. However, the relationship may result from the fact that the industrial production index serves as an indicator of a time trend. Another relationship was estimated introducing a time factor (YEAR) explicitly, as well as an index for real pharmaceutical prices--the log of the pharmaceutical price index deflated by the GNP price deflator (LPPPIR).

$$\begin{array}{lllll} \mathrm{LPHARMI} = & -0.34 & +\ 0.30(\mathrm{LINDUSTI}) & -\ 0.30(\mathrm{LPPPIR}) & +\ 0.07\ (\mathrm{YEAR}) \\ & (-1.20) & (3.57) & (-6.98) & (17.88) \\ \text{R squared} = .999 & & & & \\ \text{F ratio} = 9270.6 & & & & \end{array} \tag{2}$$

The large reduction in the coefficient of LINDUSTRI when the time variable is introduced confirms the conjecture that in Equation (1) the industrial index served as a trend indicator. The coefficient of the time variable implies a 7 percent annual growth rate in pharmaceutical production; the other coefficients imply additional positive effects on pharmaceutical production from increases in industrial production and reductions in the real price of pharmaceuticals.

To further explore the relationship between industrial production and pharmaceutical production, an equation relating the growth rates of the two variables, defined as GRI and GRP, respectively, was estimated:

$$\begin{array}{rcll} \mathrm{GRP} & = & 0.06 & +\ 0.51\ (\mathrm{GRI}) \\ & & (9.18) & (4.81) \\ \text{R squared} & = & .491 & \\ \text{F ratio} & = & 23.15 & \end{array} \tag{3}$$

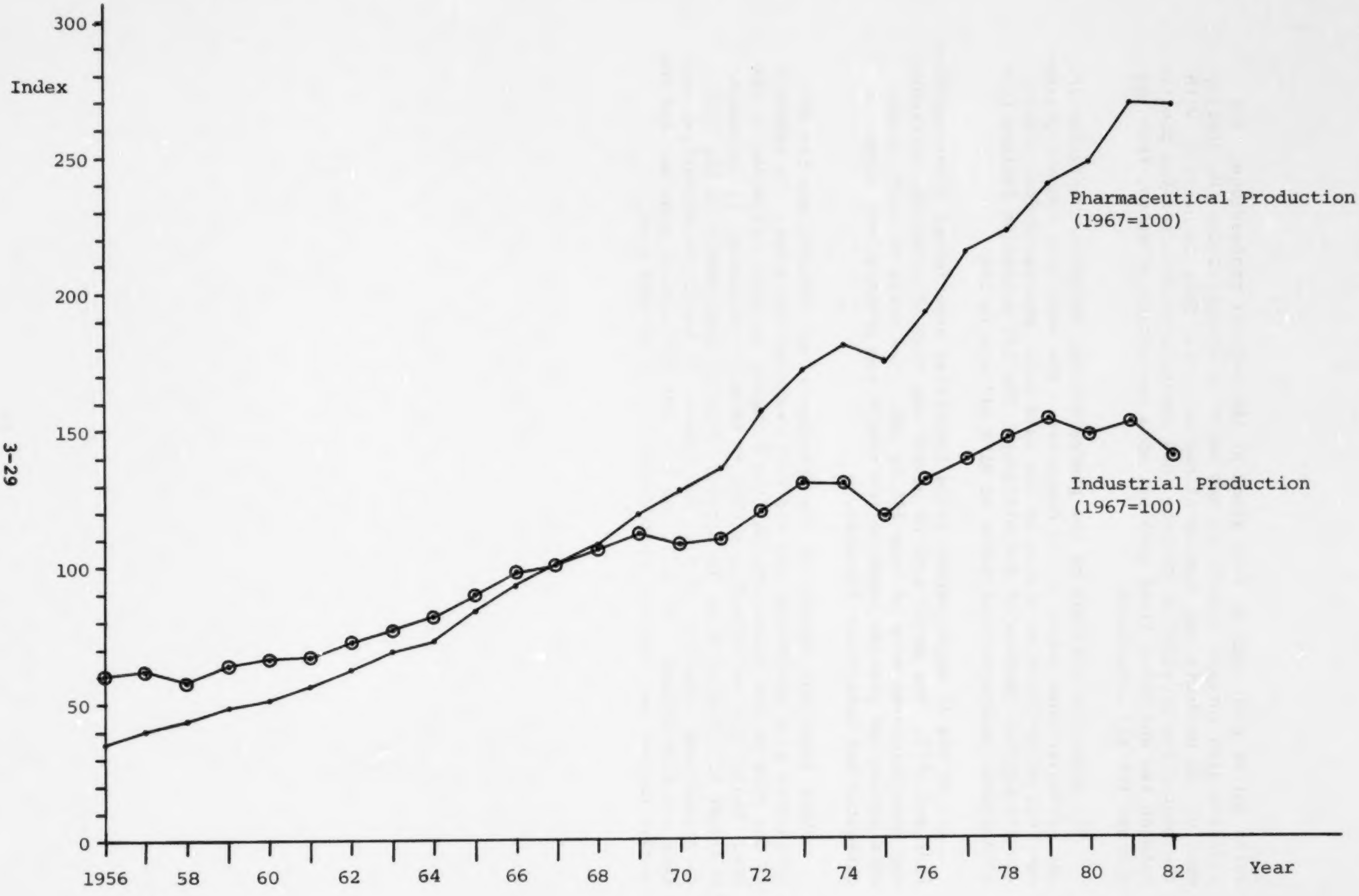
Again, the result indicates that changes in industrial production are not closely related to changes in pharmaceutical production and that there is a substantial time trend in pharmaceutical production (estimated at 6 percent a year here). Because of the strong growth trend in the industry, the effect of macroeconomic conditions on the industry tends to be dampened and play a secondary role.

Summary

The U.S. pharmaceutical industry has been defined, for the purposes of this study, as all establishments producing products classified in SICs 2831, 2833, or 2934 plus all establishments producing other pharmaceutical products classified elsewhere. Since this industry definition extends beyond the scope of conventional sources of information, some sectors of the industry lack complete data. Based on the U.S Census of Manufactures data for pharmaceutical establishments classified in the three SICs (2831, 2833, and 2834), the total value of shipments in 1977 was $14.2 billion with value added equal to $9.9 billion. Lack of data prevents an estimate of shipments for other establishments covered by the industry definition.

The industry cost structure is characterized by the large proportion of sales revenue directed toward R&D and marketing, along with substantial profit margins. Marketing alone accounts for roughly 35 percent of the

Figure 3-1. Pharmaceutical Production Index and Industrial Production Index 1956-1982



sales dollar with much of this aimed at the medical professions. The industry also invests heavily in R&D which is essential for the development of new products and opening of new markets. This innovation, with the protection provided by patents, has contributed to after-tax profits between two and three times greater, as a percentage of sales, than the average for all industries.

The Technical analysis of the pharmaceutical industry identified in 466 establishments owned by 242 companies. The mean 1980 company pharmaceutical sales based on plants in the data base (pharmaceutical plants) was $82 million (median of $10 million). The 242 companies include four with annual pharmaceutical sales of $1-2 billion in 1980.

All of the 11 major market areas identified experienced growth between 1972 and 1977. The major area of growth was that of vitamins, nutrients, and hematinics--an area of very little R&D. The areas of least growth were active and passive immunization agents and preparations affecting parasitic and infectious diseases.

Other important aspects of the pharmaceutical industry are its relationship with government and its multinational character. In addition to the role of the patent system, the industry is also influenced by the FDA. While this relationship serves to protect consumers, it increases the cost of bringing drugs to market. Foreign involvement in the U.S. pharmaceutical industry and U.S. involvement in world pharmaceutical markets are significant. In 1977, the U.S. was the largest consumer and the second largest net exporter of pharmaceuticals in that year.

Section 4

Economic Impact Methodology

This section presents the methodology, including basic assumptions and data sources, used in the analysis of the economic impact of the regulations on the pharmaceutical industry. First, the basic analytic framework is presented, followed by a discussion of the actual impact measures used.

Basic Analytic Framework

The usual measures of the economic impact of a regulation include: changes in price and quantity produced, plant closures or reductions in output and the resulting changes in the employment levels, and changes in the profitability of the firms. A demand/supply analysis for each product sector of an industry is a desirable method to produce a base case forecast of price, output, revenues over costs, and capacity utilization for each product sector in the absence of regulations. By adding the treatment costs associated with a specific regulation to the supply curve, the effects of the regulation can be forecast.

This approach was not possible for the pharmaceutical industry for several reasons. First, price determination in the standard demand/supply analysis assumes a competitive market. Due to patent protection and the use of prescriptions, a large portion of the ethical drugs market is not price-competitive. Second, neither process economics nor plant-specific production costs are available for pharmaceutical production. An alternative source of information on the cost of production might be the U.S. Census of Manufactures. However, marketing and research and development (R&D) expenditures are extremely large for this industry, making forecasts of future supply functions difficult since they are not simple cases of production cost functions inflated by appropriate indices. Future supply also will be influenced by changes in the Food and Drug Administration (FDA) regulations and procedures, and possible changes in the patent laws extending the life of a pharmaceutical patent. Third, the future demand for a product group is not a simple extrapolation of past growth rates but also is dependent on the development of new drugs and new uses for existing drugs.

Therefore, this assessment of the economic impacts focuses on current conditions, with modifications to reflect expected changes in demand and supply over the next several years. Based on the macroeconomic analysis presented in Section 3, the pharmaceutical industry is expected to continue to grow over the period the regulation is put into effect. The industry continues to show very strong growth (in terms of increased production) over time. The general business cycles seem to have only a small impact on this industry and the period in which analysis is based (1979-80) was not particularly a peak period. Therefore, the state of the industry when these regulations take affect should not be worse than the industry conditions analyzed.

Assessment of Economic Impacts

In place of a complex model of pharmaceutical production and sales, a two-step analytical procedure was employed. The first step was to screen all plants to identify those which were likely to experience a significant impact from the regulations under consideration. This step consisted of comparing the estimated treatment cost to estimated sales for each plant. Those plants whose costs exceeded one percent of sales moved on to the second step, a detailed analysis to determine their ability to comply with the regulations.* The screening and financial analysis was performed separately for each regulation, and for the combined costs of regulations.

Sources of Information

Most of the information used in the economic impact analysis was collected from publicly available sources. Additional information was provided by the Technical Contractor and from the technical 308 Survey. The Technical Contractor provided estimated treatment costs for each plant under each regulatory option analyzed.

The economic data can be grouped into three major types: plant-specific data, company data, and industry-wide data.

Plant-Specific Data

Employment for each plant was provided by the 308 Survey. Sales for most plants were provided by Economic Information Systems, Inc. (EIS). For the few plants which belong to single establishment firms and were not covered by EIS, plant sales were provided by Dun and Bradstreet. Sales for the remaining plants were estimated on the basis of employment. To do this, a regression relating sales to employment was estimated for those plants included in the EIS set, and this relationship was used to assign sales to the remaining plants. Since sales are in 1979 dollars, they are increased by a a factor of 9.5 percent to reflect inflation between 1979 and 1980. Comparisons of sales to treatment costs are made in terms of 1980 dollars.

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*The choice of one percent is discussed under Treatment Costs-to-Sales Ratio, and the detailed analysis is discussed under Closure Analysis later in this section.

Information on the products produced at each plant came from a variety of sources. The 308 Survey provided product information for some plants. Another major source of product information was the 1979 Directory of Chemical Producers, SRI International. In a few cases, this was supplemented by information found in two earlier studies.* Dun and Bradstreet and state manufacturing guides (including Puerto Rico) provided product information in some cases. For a very few plants, product information was verified by telephone calls to the plants.

Company Data

The major sources of company-level financial data were annual reports and/or 10-K reports. This information was supplemented by data from Dun and Bradstreet and from various state manufacturing and industrial guides. The International Trade Commission provided some information on which firms produced what products. Additional information was collected from the Physicians' Desk Reference**, the Merck Index***, and various trade publications+ and market studies.++

Industry-Wide Data

General information concerning the industry, its history and its growth prospects were collected from various academic studies of the industry, and the trade publications and market studies mentioned above. An additional source of industry information was the U.S. Census of Manufactures, SIC groups 2831, 2833 and 2834.

Treatment Costs

The screening measure employs the annual treatment costs. The Technical Contractor provided estimated incremental treatment costs, both capital and operating and maintenance (O&M), for each plant to meet the requirements of each regulatory option analyzed. These costs were based on model plant costs, scaled to meet the known characteristics of the actual plant. For some plants, flow and concentration levels were not known, and averages for the industry or subcategory had to be used.* Most treatment cost estimates provided by the Technical Contractor were in 1978 dollars. The cost of treatment to remove TSS and to meet the NSPS regulations were in 1980 dollars. Where necessary, costs were inflated to represent 1980 costs, based on the Engineering News Record Construction Cost Index.

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* "The Presence of Priority Pollutant Materials in the Fermentation Manufacture of Pharmaceuticals," and "The Presence of Priority Pollutants in the Synthetic Manufacture of Pharmaceuticals" submissions to EPA by PEDCo Environmental, March 1979.

** Published by: Medical Economics Co., division of Litton Industries, Oradell, NJ.

*** Published by: Merck and Company, Inc., Rahway, NJ.

+ Among which are: Drug and Cosmetics, PMA Newsletter, American Druggist, and Pharmacy Times.

++ Outlook for the Pharmaceutical Industry to 1985, 1977, Delphi Marketing Services, Inc., and The Pharmaceutical Industry, 1979, Morton Research Corporation.

Annual treatment costs are derived by converting the capital costs to an annual equivalent and adding this to the annual operating and maintenance cost. Capital costs are converted to an annual equivalent by multiplying by a capital recovery factor (CRF) which measures the rate of return an investment must achieve each year to cover the cost of the investment and maintain net earnings, including depreciation and taxes. A capital recovery factor of 0.22 was calculated, based on a 10 year life for the treatment equipment, a 15 percent cost of capital, and a five-year depreciation life for tax purposes.**

BPT Treatment Costs

The incremental treatment costs associated with the BPT option are based on the costs of removing cyanide from wastestreams and on the costs of meeting the revised limitations on total suspended solids for direct dischargers. There are five plants which will need to install additional treatment to meet the revised TSS limitations. Four plants would need to install cyanide destruction units. One of these plants also will incur TSS treatment costs, so the combined impact will result in 8 plants incurring costs.

BAT Treatment Costs

Since the cyanide limitation for BAT equals that for BPT, there are no incremental costs for BAT attributable to cyanide control. Incremental treatment costs, however, are associated with the option which would remove methylene chloride from the wastestreams of direct dischargers using steam stripping. Steam stripping removes volatile organic compounds by passing steam through the wasteflow. This option focuses on the removal of the major volatile organic compound used in the industry, methylene chloride. Costs are based on a packed column steam stripper, assuming that 26 percent of process flow is contaminated with the compound. The Technical Contractor identified fifteen plants whose wastestreams were exposed to methylene chloride and thus might need treatment. Of these, effluent data were available on ten plants. Four out of the ten plants with effluent data did not need treatment because of their low concentrations of methylene chloride. Since 60 percent (6 out of 10) of the plants with effluent data needed treatment, it was assumed that only 60 percent of the five plants without effluent data would need treatment. This probability factor was applied when calculating the expected number of plants needing treatment and the total expected cost. However, for the closure analysis, the worst case assumption was made that each plant would incur its full estimated costs.

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* A detailed discussion of the procedures employed in assigning costs to plants can be found in the development document (op. cit.).

** See Appendix C for a detailed discussion of the derivation of the capital recovery factor.

In calculating the cost of this option, a credit was allowed for the methylene chloride recovered. The credit is based on the estimated vendor price that would be paid by a solvent recovery company. The vendor price is estimated to be 65 percent of the cost of virgin methylene chloride, or 16.6 cents per pound in 1982 dollars.

PSES Treatment Costs

The incremental treatment costs are based on limiting cyanide and on limiting methylene chloride.

Cyanide Removal Costs. These were estimated in the same way as the BPT costs. Only one indirect discharger will require treatment in order to meet this regulation.

Methylene Chloride Removal Costs. These were estimated in the same way as BAT costs. There are six plants which would be certain to incur costs, based on available effluent data. In addition, there are thirty-three plants which might incur costs because they use methylene chloride but effluent data are not available. Based on the results of a June 1983 survey of sixteen (16) plants, it was assumed that 57 percent of these uncertain plants would actually incur costs.* This probability factor is used to calculate the total number of plants which are expected to incur costs and the total cost of compliance. The plant-specific impact analysis does not use the probability factor.

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* Seven (7) plants indicated the use of methylene chloride and provided concentration data. Of these, four (4) plants showed high enough concentrations to incur costs while three (3) plants did not. Therefore, it was assumed that 4/7 or 57 percent of plants without concentration data would incur costs.

Treatment Costs to Sales Ratio

This screening measure compares the annual cost of treatment to the annual sales of the plant since production costs were not available. If the ratio of costs to sales is less than one percent, then the plant is assumed to be able to finance the costs of the regulation and keep operating. In 1980, pharmaceutical companies had an after-tax profit to sales ratio of 11.3 percent. This is higher than the profit to sales ratios of most other industry groups (see Table 4-1). Therefore, an increase in costs equal to one percent of sales will leave their profit to sales ratios relatively high. By using a relatively conservative screening measure, no plant with significant impacts would be missed.

Table 4-1

Industry Profit Levels

	Ratio of After-Tax Profits to Sales (1980)
All Manufacturing	.048
Chemical and Allied Industries	.063
Industrial Chemicals and Synthetics	.045
Drugs	.113
Food & Kindred	.040

Source: U.S. Trade Commission, Quarterly Financial Report for Manufacturing, Mining, and Trade Corporations, fourth quarter 1980.

Sales figures in 1979 were obtained from Economic Information Systems (EIS) for 237 plants, out of a total 466 plants. In some cases, these sales data may be overestimates. Several plants, particularly large ones, manufacture a variety of products including non-pharmaceuticals. These other product lines tend to be industrial organic and inorganic chemicals, pesticides and dyestuffs. The sales figures for plants such as these will include non-pharmaceutical plus pharmaceutical revenues. Thus the sales would be overestimated and the economic impacts on the pharmaceuticals product group underestimated, assuming the treatment costs involve only the pharmaceutical production and not the entire plant.

EIS sales data on the remaining 229 plants were not available to us. Either EIS had assigned these plants to non-pharmaceutical SIC groups because the majority of their sales are in a non-pharmaceutical area, or the plant has fewer than 20 employees and thus is not included in the EIS data base. Of the 229 plants, 27 belonged to single-establishment firms. For these plants, since the plants and the firm are identical, sales data for the firm as reported by Dun and Bradstreet were used. For the remaining 200 plants sales were estimated based on regressions of sales on employment. Both indirect and direct discharging plants were separated into four groups based on production subcategory. Regression equations associating annual sales and manufacturing employment were then calculated for each of these four groups. Using the appropriate equation, sales were estimated for each plant. Appendix A contains a detailed discussion of the procedure and the regression results.

Closure Analysis

Additional information was collected about each plant with a cost-to-sales ratio of one percent or more. The information gathered falls into three categories:

1. Characteristics of the Parent Firm. This includes its financial strength, its major lines of business, and the relative importance of pharmaceuticals, both now and in the future.
2. Characteristics of the Specific Pharmaceutical Products Produced at the Plant. This includes the overall size and growth prospects of the products produced, and the relative competitive position of this plant in terms of factors like patent protection and their share of the market.
3. Relative Importance of Pharmaceutical Production at this Plant and the Importance of this Plant to the Company. This includes several different factors, such as what non-pharmaceutical products are produced at this plant and in what quantities, and whether the pharmaceutical products are produced by this firm at other locations.

While no formal weighting scheme is used, the second category of plant data is the most important. It is assumed that the price would increase and the plant remain in operation if the firm is in a position to pass the costs onto the consumer, due to patent protection or a very strong market position, or if all producers of that product face similar treatment costs. If these costs cannot be passed on, then a judgment has to be made as to the ability of the firm to absorb the costs. This judgment depends on the first category of information. Whether a firm is likely to make the investments is assessed in part on the basis of the third category of information. A firm is more likely to keep the plant operating if it is vertically integrated into the rest of the firm, with other plants owned by this company supplying raw materials to it and/or using its output. On the other hand, if the firm produces the same products at another location, the firm may choose to shift production from this site to another. In some cases, a firm may close down one or more production lines and leave the rest of the facility operating.

It must be stressed that these assessments are made on the basis of incomplete data and thus are subject to error. The level of detail needed in order to make very accurate assessments is not available. In particular, information about operating costs and production efficiency are not available. For many of the small, privately-held firms, very little information is available. In these cases, it may not be possible to assess the likelihood the facility will close.

New Source Impact Analysis

The methodology for analyzing impacts on new sources is somewhat different than that for existing sources, both because a different form of data are involved and because the question addressed in the analysis is different. On the first point, since the analysis deals with the impact on future construction, it is necessary to estimate costs for model plant treatment systems and to estimate the characteristics of the plants associated with those treatment systems. On the second point, the question of interest is whether there are costs, or other impacts on new sources, beyond those which a new plant would incur if it were required to comply with the requirements for existing sources.

Costs of model treatment systems were developed for several combinations of wastewater flow and industry subcategory. Sales were estimated for each combination utilizing data on existing plants by first approximating the employment for each flow/subcategory combination and then estimating sales based on the employment. The cost-to-sales ratio was then used to judge whether treatment costs might act as a barrier to new firms entering the industry or to new plant construction. A secondary impact measure was also calculated, i.e., capital investment for wastewater treatment expressed as a percent of capital investment for a new plant. Large plants (i.e., high wastewater flow) built in recent years were used as a basis for approximating plant investment. A scaling factor was used to approximate the plant investment for smaller plants. More details of the methodology are presented in Section 6.

Regulatory Flexibility Analysis

The potential impact of wastewater treatment costs on small businesses is analyzed. Employment is used as a measure of company size. Firms owning pharmaceutical plants are arranged by number of employees, from smallest to largest, and then divided into quartiles. Treatment cost impacts are then associated with the quartiles to determine the distribution of impacts among different sizes of firms.

Section 5

Economic Impact Analysis

Introduction

This section presents the results of the economic impact analysis, discussed in Section 4.* Total costs of compliance are presented for each regulation followed by a detailed description of those plants with potentially severe impacts. Probable responses by the potentially affected plants are also discussed.

The pharmaceutical industry data base for this analysis is defined by the plants included in the Technical analysis, which numbered 466 plants.** The BPT and BAT analyses examined 55 direct dischargers while the PSES analyses considered 277 indirect dischargers. Also, some plants are zero dischargers, which includes plants using deep-well injection, and are not covered by any of the regulations considered in this study. The complete breakdown of plants in the data base by type of discharge is as follows:

Direct only = 55
Indirect only = 277
Zero only = 134

Total = 466

The plants included in the BPT, BAT and PSES studies were, in part, determined by the presence and quality of the wasteflow and pollutant concentration data found in the 308 Survey reports. Many plants did not provide flow and/or concentration information, and because both of these data were necessary for estimating the treatment costs, the Technical Contractor adopted an alternate costing strategy. Costs were estimated on an "if needed" basis for those plants without complete flow and concentration data. The sum of those treatment costs was then weighted by a probability of needing treatment. It is important to note that the probability factor is used only in computing total cost of compliance for those plants without complete flow and concentration data, but not for the individual plant analyses. For the individual plant analyses, the worst case assumption was made that each plant would incur its total estimated cost.

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* See Section 2 for a more detailed description of the regulations.

** This includes 462 plants from the 464 plants included in the original 308 Survey used to analyze the proposed regulations (see Economic Analysis of Proposed Effluent Standards and Limitations for the the Pharmaceutical Industry, November 1982) plus an additional four plants.

Based on the 308 data, it was seldom possible to distinguish the relative magnitude of process flow in each discharger category for plants with multiple discharge or to determine relative pollutant concentrations in each wastestream. In such cases, the Technical Contractor has assigned the plant to either the direct or the indirect discharge category. This analysis uses the assignments made by the Technical Contractor.

Best Practicable Control Technology Currently Available (BPT)

Total Cost of Compliance

The costs associated with the BPT option cover the discharge of cyanide and total suspended solids (TSS) directly into receiving waters. Fifty-five plants discharge all or part of their wastes directly and are, therefore, subject to this regulation. The Technical Contractor determined that eight of the 55 direct dischargers would require additional treatment for compliance with this option. Four of the plants require cyanide destruction and five require treatment for total suspended solids (one plant requires both).

The Technical Contractor estimated costs for these plants. The total capital cost of compliance for the eight plants is $910 thousand. The total annual cost is $357 thousand. These, and subsequent cost figures in this section are expressed in 1980 dollars.

Plant Impacts

For each of the eight plants, the annual treatment cost was compared to annual sales. If this ratio is greater than one percent, then the impact is considered large enough to warrant further analysis. The ratios range from a high of 0.23 percent to a low of 0.01 percent, with a mean of 0.10 percent and a median of 0.11 percent. Since the highest ratios are well below 1.0 percent, no significant impacts are expected due to the BPT regulatory option. (The two plants with the highest cost-to-sales ratios under BPT appear on Table 5-1 which also presents the ratios of over 1.00 for BAT Option 2.)

Employment Impacts

Given the small cost-to-sales ratios, there should be no impact on employment.

Table 5-1. Direct Dischargers: Plants with Cost-to-Sales Ratios over 1.00 Percent for BPT, BAT Option 2 and the Combination

Plant ID	Cost-to-Sales Ratio (Percent)		
	BPT	BAT Option 2	BPT & BAT Option 2
Plant D 1	0.00	3.24	3.24
Plant D 2	0.23	2.48	2.70
Plant D 3	0.20	2.26	2.47
Plant D 4	0.00	2.17	2.17
Plant D 5	0.00	1.29	1.29
Plant D 6	0.00	1.25	1.25
Plant D 7	0.00	1.14	1.14

Price Changes

Due to the lack of data and to the complexity of the pharmaceutical industry, it was not feasible to estimate price elasticities. Instead, it was assumed that for products with patent protection, the costs would be completely passed through as price increases without loss in sales volume. For some plants, product information was available. However, the actual output levels for these products were not available. Therefore, a specific price increase due to a cost increase could not be estimated. As an extreme position, it was assumed that all firms would transfer the entire cost of the regulation into higher prices. The annual cost of the BPT option is about $357 thousand. Given estimated total sales of $972 million for the 8 direct discharging plants incurring costs, the cost-to-sales ratio for BPT Option 1 would then be:

$$\$0.357 \text{ million}/\$972 \text{ million} = 0.04 \text{ percent}$$

Clearly this is very rough and should be taken as no more than an order of magnitude estimate. Total sales include some non-pharmaceutical sales which may cause this to be an underestimate. Conversely, not all firms will be able to shift their costs into price increases. Sufficient data are not available with which to determine those specific types of products that may bear disproportionate costs.

Balance of Trade Impacts

As described in Section 3, "Industry Profile", the United States is the second largest exporter of pharmaceuticals. In 1977, U.S. exports represented about 9 percent of the total value of shipments. The impact of this BPT regulation should be very small given the small impact on prices estimated above.

Best Available Technology Economically Achievable (BAT)

The cyanide concentration limit for BAT is equal to the BPT cyanide limit. Assuming BPT treatment is in place, no additional cyanide removal is necessary and no costs are incurred for BAT Option 1. Addition of the methylene chloride limits under BAT Option 2 requires steam stripping. The costs and impacts resulting from regulating methylene chloride are discussed next.

Total Cost of Compliance

The Technical Contractor identified fifteen plants which might need to install steam stripping to remove methylene chloride. Of these fifteen, concentration data were available for ten. Six of the ten (60 percent) would incur costs while the other four would not due to their current low methylene chloride concentrations. Concentration data were not available for five of the plants. In these cases, costs were estimated based on average numbers. Since 60 percent of the first set needed treatment, it was assumed that 60 percent of the second set would also need treatment. Therefore, a total of nine plants are expected to need steam stripping treatment, and the total cost of compliance equals the total cost for the first set plus 60 percent of the total cost for the second set.

The total capital cost of compliance for the nine plants expected to incur costs under BAT Option 2 is $5.751 million. The total annual cost of compliance for these plants is estimated at $5.483 million ($5.588 million for treatment less a credit for recovered methylene chloride of $105 thousand*).

Plant Impacts

The annual cost of compliance is compared to the annual sales for each plant. If this ratio is greater than one percent, then the impact is considered large enough to warrant further analysis. Since it is unknown which three of the second set of five plants will bear steam stripping costs, the worst case assumption is made that each plant will bear its full estimated costs. Therefore, a total of 11 plants have steam stripping cost estimates (six that would definitely incur costs, and five possibles).

The cost-to-sales ratios range from a high 3.24 percent to a low of 0.6 percent, with a mean of 1.33 percent and a median of 1.25 percent. Seven of the 11 plants have a cost-to-sales ratio of one percent or greater (see Table 5-1) and they were examined in more detail to identify the possibility of closures, as explained below.

Closure Analysis

The direct discharge plants incurring the largest and third largest cost-to-sales ratios under this option (3.24 and 2.26 percent) are both owned by the same large company. These plants (plants D 1 and D 3) employ about 250 and 400 pharmaceutical employees. Both plants produce a wide variety of medicinals. Because of the size of the plants, the range of products, and the size of the parent company (approximately 30,000 employees), the plants are not expected to close, although they both have relatively large cost-to-sales ratios.

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* The 1982 value of recovered methylene chloride of 16.6 cents per pound was adjusted to a 1980 value in order to be compatible with 1980 treatment costs and plant sales estimates used in this section.

Another large chemical company owns the plants with the second and fifth largest cost-to-sales ratios, which are 2.48 and 1.29 percent. One plant (D 2) manufactures fertilizers and pesticides as its primary products. Only 25 of about 350 total plant employees are involved in medicinal manufacture. If the parent company produces the single pharmaceutical manufactured here at other plants, it is possible, but unlikely that production of the chemical would be moved to the second location. If the company does not produce the chemical at another plant, it is possible, but even less likely, that the plant would close their medicinal line of production.

The company's second plant with a cost-to-sales ratio greater than 1.00 percent (plant D 5 at 1.29 percent) is fairly large (close to 175 employees), and produces a wide variety of products. The parent company is strong, with 1982 sales at about $3,500 million, with medical sales accounting for about 40 percent of corporate operational earnings. Because of these strengths, and because the cost-to-sales ratio is close to one percent, closure of the plant is not anticipated in response to the regulation.

One large chemical company owns four plants which incur costs under this regulation; one of these plants has the fourth largest cost-to-sales ratio, another the seventh. The plant with the fourth largest cost-to-sales ratio (plant D 4 at 2.17 percent) is relatively new (built in the late 1970's) and is located in Puerto Rico. While the tax advantages of a Puerto Rican location have been reduced, these plants still tend to be very profitable. This and its newness make it unlikely to be closed.

Plant D 7, with the seventh highest cost-to-sales ratio (owned by the same large chemical company which owns plant D 4), is very large (about 1,000 employees), produces 31 medicinal and 46 other chemicals, and has a marginal cost-to-sales ratio (1.14 percent). The plant is not expected to close.

The plant with the sixth highest cost-to-sales ratio at 1.25 percent (Plant D 6) is owned by a slightly smaller company with about 3,500 employees. The plant itself employs about 400 workers. Because its ratio is marginal, and the plant and corporation are fairly large, the BAT regulation is not expected to result in a closure of this plant.

Employment Impacts

Since there are no expected plant nor product line closures, there will be no impact on employment.

Price Impacts

It is not possible to estimate price increases for specific products. As an extreme case, it is assumed that the total cost of the regulation is passed on by firms in the form of higher prices. Given the total estimated sales of $837 million for the nine direct dischargers expected to incur costs, the total cost-to-sales ratio for BAT Option 2 would be:

$5.48 million/$837 million = 0.65 percent

This is a very rough estimate of the price impact. Total sales include some non-pharmaceutical sales; also, not all firms can shift their costs forward. In addition, the treatment costs may be concentrated in certain product groups. However, it appears that any price increases are likely to be small.

Balance of Trade Impacts

Given the very small price impacts of BAT Option 2, there is likely to be little or no overall impact on the balance of trade. As with the other regulations, this conclusion may not hold for specific pharmaceuticals where the price impact and competition may be significantly greater than the average levels.

BPT Combined with BAT

This section considers the combined economic effects of BAT Option 2 and BPT on direct dischargers.

Total Cost of Compliance

A total of 14 plants incur costs as a result of BPT combined with the BAT option which would limit methylene chloride. Three of these plants require treatment under both BPT and BAT Option 2. The total capital cost of compliance is $6.661 million, and the total annual cost is $5.840 million ($5.945 million for treatment less a credit of $105 thousand for recovered methylene chloride).

Plants Impacts

Plant impacts under the combined regulations are relatively unchanged from plant impacts described under BAT Option 2. This is because the BPT cost-to-sales ratios are fairly insignificant (see Table 5-1). All the plants which attain cost-to-sales ratios greater than one percent under the combined options also exceeded the one percent criterion under BAT Option 2 alone.

Employment Impacts

As in the case with the separate BPT and BAT analyses, no employment impacts are expected.

Price Impacts

As with the separate BAT and BPT analyses, it appears that price impacts will be small.

Balance of Trade Impacts

As the impacts are similar to impacts under BAT Option 2, conclusions drawn in that section also apply to the combined BAT and BPT impacts.

Pretreatment Standards for Existing Sources (PSES)

There are two PSES options for indirect dischargers. One of these options limits only cyanide concentrations in the wastestream. Only one plant would have costs for compliance with this option (PSES Option 1). The second option (PSES Option 2) limits cyanide and methylene chloride. One plant incurs cyanide treatment costs and methylene chloride treatment costs, five plants have only methylene chloride treatment costs, and 33 plants may have methylene chloride treatment costs. Methylene chloride concentration data were unavailable for these 33 plants, so the expected number of plants incurring costs was estimated.

Total Cost of Compliance

In a 308 Survey done in June 1983, four of seven plants which used methylene chloride in production showed high enough concentrations of the chemical to incur costs under PSES Option 2. Thus, four-sevenths (or approximately 57 percent) of the 33 plants (i.e., 19 plants) using methylene chloride but without concentration data are assumed to have PSES Option 2 compliance costs. Plant specific costs were estimated based on flows for the given plants and average concentrations.

The total capital cost for PSES Option 1 is $360 thousand and the total annual cost is $223 thousand. For PSES Option 2, the total capital cost of compliance for the 25 plants expected to incur costs is $16.568 million, the total annual cost is $16.289 million ($16.885 million less a credit for recovered methylene chloride of $596 thousand). These costs are shown in Table 5-2.

Table 5-2. Cost of Compliance for PSES Options

(Thousands of 1980 dollars)

	PSES Option 1			PSES Option 2		
	No. of Plants*	Capital Costs	Annual Costs	No. of Plants*	Capital Costs	Annual Costs
Cyanide Control	1	$360	$223	1	$360	$223
Methylene Chloride Control	NA	NA	NA	25 **	$16,208	$16,662
Cost of Option	-	$360	223	-	$16,568	$16,885
Credit for Methylene Chloride Recovered						596
Totals						
Plants Incuring Costs	1			25 **		
Cost of Compliance		$360	$223		$16,568	$16,289

NA = Not applicable.

* Number of plants expected to incur treatment costs.

** One plant incurring cost for methylene chloride control also incurs cost for cyanide control.

Plant Impacts

As with the BAT and BPT options, annual cost of compliance is compared to the annual sales for each plant. In the case of PSES Option 2, since it is unknown which 19 of the 33 plants without concentration data may incur costs under the regulation, the worst case assumption is made that each plant will bear its full estimated costs. Therefore, a total of 39 plants are analyzed under PSES Option 2.

Under PSES Option 1, the only plant which incurs cost has a cost-to-sales ratio of 0.16 percent. This is a very small economic effect. Under PSES Option 2, the cost-to-sales ratios range from a high of 11.89 percent to a low of .04 percent. The mean cost-to-sales ratio for PSES Option 2 compliance is 0.90 percent, and the median is 0.37 percent. Five plants have cost-to-sales ratios of over one percent, and three of these plants have ratios of over two percent as shown in Table 5-3.

Table 5-3. Indirect Dischargers: Plants with Cost-to-Sales Ratios over 1.00 Percent for PSES Option 2

Plant ID	Cost-to-Sales (Percent)
I 1	11.89
I 2	9.70
I 3	2.05
I 4	1.98
I 5	1.26

Closure Analysis

For the five plants having cost-to-sales ratios over one percent under Option 2, a closure analysis was carried out.

The plant with the highest cost-to-sales ratio (Plant I 1), is a relatively small establishment (81 employees) which produces medicinal and industrial organic chemicals as well as custom synthesis of chemicals. Given its relatively large cost-to-sales ratio (11.89 percent) it might close in response to this regulation.

The plant incurring the second highest cost to sales ratio (Plant I 2 at 9.70 percent) is owned by a large pharmaceutical company. It is a very large plant, employing around 9,000 workers. In addition to pharmaceuticals and vitamins, the plant also produces hair care products, chemicals, cosmetics, and diagnostic products. It is also a major research facility, dealing with pharmaceuticals, vitamins, and fine chemicals. Given the large size of the facility, its importance to the firm and the firm's financial condition, it will not close.

Plant number I 3 has the third largest cost-to-sales ratio under PSES Option 2, of 2.05 percent. It is a relatively large plant owned by a large chemical company. Since medicinal chemicals are the firm's most important product line, we do not expect the plant to close.

Plant I 4 is a small formulating plant, owned by a relatively small firm which also has facilities in foreign countries. With the fourth largest cost-to-sales ratio under this regulation of 1.98 percent, this plant will bear a significant impact. However, it is not expected to close.

There are no plant or corporate data available on the fifth and last plant (I 5) incurring a cost-to-sales ratio of greater than one percent. However, since the ratio is relatively small at 1.26 percent, we do not expect closure.

Employment Losses

As a percent of total unemployment, the possible employment loss is zero under Option 1 and very small (0.09 percent) under Option 2 (see Table 5-4). The size of the only plant which may close is 81 employees. Employment figures are from the 1978 and 1979 308 Surveys.

Price Changes

It was not possible to estimate price increases for specific products. As an extreme case, it was assumed that the total cost of the regulation would be passed on by firms in the form of higher prices. Given total estimated sales of $3.64 billion for the 25 indirect dischargers expected to incur costs, the total cost-to-sales ratio for PSES Option 2 would be:

$16.29 million/$3,640 million = 0.45 percent

Therefore the price impact would be small. This is a very rough estimate. Total sales include some non-pharmaceutical sales, while not all firms can shift their costs forward. In addition, the treatment costs may be concentrated in certain product groups. However, it appears that any price increases are likely to be small.

Balance of Trade Impacts

Given the very small price impacts of the PSES options, there is likely to be little or no overall impact on the pharmaceutical balance of trade. As with the BPT option, this conclusion may not hold for specific pharmaceuticals where the price impact and competition may be significantly greater than the overall levels.

Table 5-4. Plant Employment Impacts--PSES Option 2

Total number of employees, all indirect dischargers. (280 plants)	93,500
Total employees lost due to possible plant closures *	81
Total employees lost due to possible closures of pharmaceutical production lines	0
Employees lost/total employees (percent)	0.09

* Plant I 1.

Section 6

New Source Performance Standards (NSPS) and Pretreatment Standards for New Sources (PSNS)

The analysis presented in this section addresses the following topics: (1) NSPS and PSNS options, (2) costs of model treatment systems for the options, (3) characteristics of pharmaceutical plants associated with the options, (4) impacts of treatment costs, and (5) prospects for new plant construction. The impacts are based on treatment costs beyond those that would be incurred if new sources only had to meet the requirements that pertain to existing sources. The impact of these additional costs for new sources might act as a barrier to new firms entering the pharmaceutical industry or to firms already in the industry who might otherwise build new production facilities.*

Description of Options

The November 26, 1982 proposed regulation includes NSPS limitations for BOD_5, TSS, COD, pH and cyanide. The promulgation of the COD limitations is being deferred. Limitations for pH and cyanide are the same for new and existing sources. Hence, this analysis focuses on options for the treatment of conventional pollutants, BOD_5 and TSS. Two options were developed by the Technical Contractor: Option A is based on biological treatment alone, and Option B is based on biological treatment with filtration.

While the same technologies are applicable across industry subcategories,** the effluent limitations, flows and costs are different. For example, pharmaceuticals produced by fermentation processes generates significantly higher wastewater pollutant loads than those generated by biological extraction processes. For the NSPS analysis, two sets of costs were developed: one set is applicable to Subcategories A and C (fermentation and chemical syntheses processes that generate relatively high pollutant loads) and one set that is applicable to Subcategories B and D (biological extraction processes and formulation plants). Different flow rates, indicative of different sizes of pharmaceutical plants, are considered for each of the two sets.

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* The analysis assumes that the NSPS costs incurred for a major modification to an existing source would not be greater than the treatment cost for a new source.

** Industry subcategories, covered by these NSPS options, based on production process, are: A = Fermentation, B = Biological Extraction, C = Chemical Syntheses, D = Formulation.

The PSNS option, which imposes the same effluent limitations applicable to existing indirect dischargers under PSES, is considered briefly.

Cost Estimates

The NSPS costs as provided by the Technical Contractor, appear in Table 6-1. Plants in Subcategories A and C have the same treatment costs and plants in Subcategories B and D have the same cost. For plants in Subcategories A and C, three flow rates are considered (0.10, 0.50 and 1.202 MGD), representing low, median and high flow rates. Because flows and costs tend to be smaller, only one flow rate is considered (0.05 MGD) for plants in Subcategories B and D, which approximates the median flow of existing plants in those subcategories.

The capital and annual costs shown first in Table 6-1 are the total expenditures to attain NSPS while the relevant cost for the impact assessment is the additional--or incremental--cost, over and above the cost to achieve BPT standards. For plants in Subcategories A and C, the incremental capital costs range from $93 thousand to $2.301 million, while for plants in Subcategories B and D, the range is from $43 to $271 thousand. Incremental annual costs for Subcategories A and C plants range from $31 to $635 thousand and for Subcategory B and D plants, the range is $12 to $70 thousand.

For PSNS, there are no incremental costs because the pretreatment standards are the same as those for existing sources.

Plant Characteristics

The primary measure of the potential impact of NSPS regulation is the ratio of annual incremental treatment cost to plant sales. To estimate plant sales associated with particular subcategories and wastewater flows, relationships were established between flow, employment and sales. The relationships are based on existing pharmaceutical plants. The development of the relationship between sales and employment is presented in Appendix A.

An intermediate step was required to first estimate number of employees appropriate to model plants representative of wastewater flows for model treatment systems selected by the Technical Contractor. The employment estimates are based on the relationship between employment and flow observed in the sample of plants used by the Technical Contractor as the basis for the model treatment systems, as well as the employment/flow relationship among existing A, C and B, D plants that are direct dischargers.

Table 6-1. Cost to Meet New Source Performance Standards
(Costs are in thousands of 1982 dollars)

	Subcategories A and C		Subcategories B and D	
	Option A	Option B	Option A	Option B
Flow (MGD)	0.10	0.10		
Capital cost - Total	3,480	3,797		
Annual cost - Total	1,020	1,102		
Capital Cost - Incremental*	93	410		
Annual cost - Incremental*	31	113		
Flow (MGD)	0.50	0.50	0.05	0.05
Capital cost - Total	8,036	8,806	2,069	2,297
Annual cost - Total	2,509	2,711	579	637
Capital cost - Incremental*	358	1,128	43	271
Annual cost - Incremental*	169	371	12	70
Flow (MGD)	1.202	1.202		
Capital cost - Total	14,115	15,147		
Annual cost - Total	4,678	4,957		
Capital cost - Incremental*	1,269	2,301		
Annual cost - Incremental *	356	635		

Notes: Subcategories: A = Fermentation, B = Biological Extraction, C = Chemical Synthesis, D = Formulation.

Option A = Advanced biological treatment.
Option B = Advanced biological treatment with filtration.

* Incremental cost is the amount over and above the treatment cost to achieve BPT standards.

Having estimated the employment for the model plants, the equations in Table A-3 of Appendix A were used to estimate sales. For plants in Subcategories A and C, two estimating relationships (i.e., equations) are necessary to describe different groupings of existing plants and result in a low and high value of plant sales. For plants in Subcategories B and D one equation is used to estimate the plant sales, as described in the Appendix A. Since the equations estimate sales in 1979 dollars, the resulting estimates were escalated to 1982 dollars and are presented in Table 6-2.

A secondary indicator of the impact of NSPS is the ratio of the capital cost for wastewater treatment to the construction cost of a new plant. (Again, the relevant treatment cost is the incremental capital cost for NSPS beyond the capital cost of achieving BPT standards.) To estimate the new plant construction costs, two approaches were considered. Based on announcements of new production capacity from April 1981 through July 1983, the cost to build a new formulating plant (Subcategory D) is approximately $30 million and to build a manufacturing facility (Subcategory unspecified) is from $30 to $55 million.* However, it is not possible to estimate the size of plant or sales from the announcements. Therefore, a second approach was used.

In the second approach, the opinion of an engineering firm familar with pharmaceutical plant designs was sought. Based on a large fermentation plant (Subcategory A) completed in 1968, with a flow of 1.1 MGD and manufacturing employment of 350, the investment for a new plant is estimated at $125 million in 1982 dollars. Investment in a large plant in Subcategory B or D (defined by a flow of about 1.0 MGD) is estimated at $60 million based on a large new formulation plant that was completed in the past year. For Subcategory A and C, it is assumed that the highest flow rate model plant (1.202 MGD) is indicative of a new plant that requires a capital investment of $125 million and produces annual sales of $76.24 to $91.97 million. For the two smaller model plants (0.5 and 0.1 MGD), the capital investment is estimated from the larger plant investment and an exponential scale factor of 0.6 where plant sales is assumed to be a relevant indicator of plant size. That is, the capital investment for a smaller plant is $125 million multiplied by $(S_2/S_1)^{0.6}$ where S_1 is the sales for the large plant and S_2 is the sales for the small plant. For Subcategory B and D plants, we assume that a flow rate of 1.0 MGD is indicative of a large new plant that requires a capital investment of $60 million and generates sales of about $200 million. However, the model plant has a flow of only 0.05 MGD. Again, a scaling factor of 0.6 is applied to the ratio of plant sales to estimate the investment for the model plant of 0.05 MGD. Table 6-3 shows the new plant capital investment estimates for the three model plants in Subcategory A and C and the one model plant in Subcategory B and D. (The sales figures used in scaling down the largest plant investment are the values shown in Table 6-2.)

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* Drug and Cosmetic Industry, April 1981 through July 1983.

Table 6-2. Plant Characteristics for NSPS Analysis
(Sales are Millions of 1982 Dollars)

	Subcategories A and C	Subcategories B and D
Flow (MGD)	0.10	
Employment	50	
Sales (millions of 1982$)	$19.916 to $25.565	
Flow (MGD)	0.50	0.05
Employment	160	250
Sales (millions of 1982$)	$40.569 to $49.915	$50.010
Flow (MGD)	1.202	
Employment	350	
Sales (millions of 1982$)	$76.241 to $91.974	

Notes: Sales are in 1982 dollars.

Employment and Sales for a given flow are applicable to both Option A and B.

Table 6-3. Estimates of Capital Investment for New Plants (Costs are millions of 1982 dollars)

	Subcategories A and C	Subcategories B and D
Flow (MGD)	0.1	
Capital Investment (millions of 1982$)	$56	
Flow (MGD)	0.5	0.05
Capital Investment (millions of 1982$)	$86	$26
Flow (MGD)	1.202	
Capital Investment (millions of 1982$)	$125	

Impacts of Treatment Costs for NSPS

Using the sales estimates presented in Table 6-2 and the annual treatment cost (incremental) shown in Table 6-1, sales to treatment cost ratios were calculated. The cost-to-sales ratios are summarized in Table 6-4.

For Subcategory A and C plants, the treatment cost-to-sales ratio for Option A ranges from 0.12 percent to 0.47 percent depending on the model plant wastewater flow. For the more stringent standard, Option B, the cost-to-sales range is 0.44 to 0.91 percent.

For Subcategory B and D plants, the ratio for Option A is 0.024 percent. For Option B, the ratio is 0.14 percent.

Considering Subcategory A and C, the smaller plants (based on wastewater flow) generally show the least impact in terms of the cost-to-sales ratio. Regardless of subcategory or wastewater flow, all model plants show a treatment cost-to-sales ratio that is less than one percent.

The secondary impact measure--capital cost for wastewater treatment compared to total capital investment for a new plant--is shown in Table 6-5. For Subcategory A and C plants, the NSPS Option A capital investment for treatment is between 0.17 and 1.02 percent of plant investment and between 0.73 and 1.84 percent for Option B. For Subcategory B and D plants, the ratio is between 0.17 percent and 1.04 percent depending on the option selected.

Based on the two measures of impact--treatment cost as a percent of sales and the capital cost for treatment as a percent of total plant investment for a new plant--it does not appear that NSPS will impose a significant barrier for firms contemplating the construction of new pharmaceutical plants. Moreover, in building new plants, firms will have a choice between direct discharge or utilization of POTW's. If NSPS costs are considered too high, the firm could select the POTW option. This option may result in lower costs than NSPS because pretreatment standards for new sources are equivalent to PSES for existing plants.

Prospects for New Plants

Expansion of plant production capacity over the next few years is not expected to be large, even if no new water quality regulations are imposed. Capacity utilization in the late 1970's was low due to rapid expansion during a period of relatively low growth in demand. Capacity utilization in 1977 was only 72 percent, as compared with 77 percent in 1976 and 80 percent in 1974.* Expected low levels of expansions are

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* The Pharmaceutical Industry, March 1979, the Morton Research Corporation.

Table 6-4. NSPS Cost-to-Sales Ratios for Model Plants (Cost and Sales in 1982 dollars)

Treatment Level	Flow (MGD)	Annual Cost Incremental ($000's)	Cost-to-Sales (Percent)
Subcategory A and C			
NSPS, Option A	0.1	31	0.16 to 0.12
	0.5	169	0.42 to 0.34
	1.202	356	0.47 to 0.39
NSPS, Option B	0.1	113	0.57 to 0.44
	0.5	371	0.91 to 0.74
	1.202	635	0.83 to 0.69
Subcategory B and D			
NSPS, Option A	0.05	12	0.024
NSPS, Option B	0.05	70	0.14

Table 6-5. Ratio of NSPS Capital Cost for Wastewater Treatment to Total Plant Investment

Treatment Level	Flow (MGD)	Capital Cost for Treatment as a Percent of Total Plant Investment (Percent)
Subcategory A and C		
NSPS	0.1	0.17
	0.5	0.42
	1.202	1.02
NSPS, Option B	0.1	0.73
	0.5	1.31
	1.202	1.84
Subcategory B and D		
NSPS, Option A	0.05	0.17
NSPS, Option B	0.05	1.04

further supported by the analysis of recently announced expansions and new plant construction mentioned earlier. For purposes of this study, facilities were categorized as follows: research and development, manufacturing, formulating, and unspecified. Over the 28 month period, there were 52 announced expansions and new facilities, with completion dates ranging from 1981 through 1985. However, 14 of these were solely research and development facilities. Research and development facilities produce very little wastewater and are not included in the coverage of the NSPS options. Of the 38 remaining announcements, the largest group is manufacturing, with 26 new or expanded plants. Two of these also have R&D facilities. In comparison, formulating will be experiencing very little expansion, with only 8 new or expanded facilities announced. Two of these also include research and development facilties. For the remaining four announcements, the use of the facility was not specified.*

Given that 34 new manufacturing and formulation plants were announced over the 28-month period, the current rate of plant construction is about 15 per year. It is estimated that 20 percent of these will be direct dischargers (three plants per year). Assuming they are evenly divided into the A, C and B, D Subcategories, and that the plants constructed in Subcategory A and C are of the largest size costed above, the estimated incremental capital costs of the NSPS Option B regulation would be $3.9 million/year and incremental annual costs would be $1.1 million/year for the three new plants.

PSNS

The impact analysis discussed above pertains to direct dischargers. Because pretreatment standards for new sources are the same as those for existing sources (PSES), there are no incremental costs. Therefore, no economic impact analysis was undertaken.

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* This compilation of new plant announcements is consistent with Census information showing substantially higher annual growth rates over the last ten years in the manufacturing segments (SIC 2831, Biological Products and SIC 2833, Medicinals and Botanicals) than in formulation (SIC 2834, Pharmaceutical Preparations).

Section 7

Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act of 1980, the EPA and other regulatory agencies are required to consider the effects of proposed regulations on small companies. This section reviews the potential small business impacts of the Promulgated Regulations on the pharmaceutical industry.

Definition of a Small Firm

The Act relies on the Small Business Administration (SBA) for guidance in defining a small firm. The Small Business Act, section three, defines a small business as:

> "...a small business concern shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation. In addition to the foregoing criteria, the Administration (of the SBA), in making a detailed definition may use these criteria, among others: number of employees and dollar volume of business."

In addition, the SBA has published specific employee based guidelines for various business activities including manufacturing. For companies classified in SIC 2834, the SBA defined a small firm as one with not more than 750 employees.* Companies classified in SICs 2831 and 2833 with not more than 250 employees are considered small. For the purposes of this analysis, even 250 employees may be large, given that the Regulatory Flexibility Act is concerned with firms with limited resources and avoiding regulatory barriers to entry into an industry.

As described in Section 3, the pharmaceutical industry is characterized by a large number of small firms, most of which own one facility, and a few number of large firms which each own several facilities. The 308 Survey covered 466 plants owned by 242 firms. Arranging the firms by number of employees, from smallest to largest, and then dividing the firms into quartiles shows how dominant these large firms are in terms of number of plants (see Table 7-1).**

In the first quartile, each firm has only one facility. In the second, each firm has an average 1.10 plants. However, the firms in the fourth quartile have an average 4.18 plants. Therefore, a large percentage of the firms employ only a small percentage of the workers and

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* Code of Federal Regulations, Title 13, Section 122.3-10.

** For 19 firms, employment could be determined only within a range.

Table 7-1. Size Distribution of Pharmaceutical Companies

Firms Arranged by Number of Employees, From Smallest+	Firm Employment Range	Number of Plants Owned by Firms in This Quartile
First Quartile	3-31	61
Second Quartile	32-115	66
Third Quartile	116-4,801	88
Fourth Quartile	4,802-402,000	251

+ Each Quartile is comprised of 60 or 61 firms.

control only a small percent of the production.* In place of setting a single definition of small business, the cost data has been arrayed for each regulation, by the employment size quartiles given above. See Table 7-2.

BPT Option

The smallest firm which may bear treatment costs under BPT is in the third quartile, with corporate employment of about 2,000. The remainder are in the fourth quartile. Therefore, this option has no small business impact.

BAT Options

For BAT Option 1, the cyanide limit is the same as BPT and there are no incremental costs. Under Option 2, which would add the control of methylene chloride, the smallest firm which bears treatment costs under this regulation is in the third quartile, employing 3,500 personnel. The remaining companies are in the fourth quartile. Therefore, this option has no small business impact.

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* Sales and employment are highly correlated for this industry, see Section 3.

Table 7-2. Distribution of Firms With Treatment Costs, by Employment Size*

Firms Arranged by Number of Employees, from Smallest	BPT	BAT Option 2**	PSES Option 1	PSES Option 2	Sum of BPT, BAT Option 2 and PSES Option 1+	Sum of BPT, BAT Option 2 and PSES Option 2+
First Quartile	0	0	0	1	0	1
Second Quartile	0	0	0	1	0	1
Third Quartile	1	1	1	9	2	10
Fourth Quartile	6	6	0	19	6	21
Total Number of Firms with Treatment Costs*	7	7	1	30	8	33

* The probability factor is not applied (see Section 5). Therefore, the worst case assumption is used here i.e.; that all plants who might have to bear costs, do incur them.

** Since BAT Option 1 is equal to BPT, there are no additional costs.

+ Rows do not sum because a single firm may bear costs under more than one proposed regulation. This column presents the total number of firms in each employment quartile which bear costs under the options listed.

PSES Options

Only one firm bears costs under PSES Option 1. This firm is in the third quartile, and is not a small business. One firm in each of the two quartiles of firms with the smallest employment bears costs under PSES Option 2. Nine firms in the third quartile bear costs and 19 firms in the quartile with the largest employment bear costs. Thus, in terms of the distribution of costs, large firms bear a much greater share of the costs.

A second measure of the distributution of the burden of PSES Option 2 is a comparison of the average cost-to-sales ratios for the firms bearing costs in each quartile. This overestimates the impact, since firms which do not have any costs are not included in calculating the average. The average cost-to-sales ratios for firms bearing costs under this regulation are:

	PSES Cost-to-Sales (Percent)
First Quartile	1.98
Second Quartile	11.89
Third Quartile	0.60
Fourth Quartile	0.73

Of the firms which bear costs, small firms have higher cost-to-sales ratios than larger firms. A much larger proportion of large firms have costs, but the two smallest firms are most highly affected by this regulation.

A third measure of the distribution of the burden of these regulations is a comparison of possible closures across size quartiles. The one possible plant closure belongs to a small business, in the second quartile; this is projected under PSES Option 2.

BPT, BAT and PSES Combined

To sum up the impact under BPT, BAT Option 1 and PSES Option 1, no firms in the smallest two quartiles are expected to incur costs. For the corresponding figures with control of methylene chloride only two firms out of the smallest 122 firms (1.6 percent) bear costs, while 40 of the largest firms (32.8 percent) bear costs. Again, the highest cost-to-sales ratios tend to be concentrated among those smaller firms which do bear costs, and the only plant that is a closure candidate is owned by a small firm. Therefore, only a relatively few small firms bear costs, but to them the burden is large.

NSPS

It is not possible to predict the potential impact of new source standards on small businesses from the available information. However, several observations can be made based on characteristics of the industry described in Section 3 and on the analysis of NSPS cost impacts in Section 6.

It is unlikely that small firms will build large plants, therefore the cost-to-sales ratios developed in Section 6 that are most relevant to small firms, are for the low flow (i.e., small size) model plants. (The three model plants in Subcategories A and C are estimated to have 50, 160 and 350 employees and would fall in the second and third quartiles assuming the firm owns only one plant. The model plant in Subcategories B and D has 250 employees and therefore is in the third quartile.) The smallest plants show the least impact in terms of treatment cost as a percent of sales and furthermore none of the model plants has a cost-to-sales ratio greater than 0.91 percent. Thus, it does not appear that small companies will bear a disproportionate share of the treatment costs for new plants. In addition, it should be pointed out that this option applies to direct dischargers, while most of the existing small plants are indirect or zero dischargers (e.g., 92 percent of the plants with under 100 workers are zero or indirect dischargers). Hence, the NSPS requirements are unlikely to have a bearing on entry or construction decisions of small firms.

Section 8

Limits of the Analysis

This chapter examines various problems and shortcomings in the analysis and recommends certain cautions in applying the results. Two basic types of problems were found: problems with the data used in the analysis and methodological problems.

Definition of the Industry and Sample Size

The total cost of compliance for the industry was calculated on the basis of the sample of establishments used for the Technical 308 Survey. This total cost may be subject to upward revision depending on the comprehensiveness of the sample of establishments. Compared with data provided by the U.S. Census of Manufactures, the survey sample of 464 establishments appears small. This sample includes 306 establishments classified in SICs 2831, 2833, and 2834 which accounted for $13.6 billion in 1979 sales. The remaining 158 establishments in the sample totalled $6.0 billion in 1979 sales. In contrast the estimated 1979 Census figures for SICs 2831, 2833, and 2834 report value of shipments of $17.3 billion for 1,243 establishments.* Therefore compared to the Census figures, the survey sample includes a quarter of the establishments and almost three quarters of sales. No comparison can be made for establishments in other SICs.

The comparison of Census and 308 Survey figures suggests that the latter missed many small establishments. To determine whether this was so and to assess the effect this might have on the conclusions of the present report, an analysis of the two 308 Surveys was carried out. The first survey included the PMA membership and other plants--mostly large plants--known to EPA from earlier guideline work. The second survey was based on an extensive search for additional plant names from industrial directories and other sources. The plants in the second survey were much smaller on the average (average employment of 43 vs. average employment of 300). Moreover, a much larger fraction were zero dischargers (50 percent vs. 9 percent in the first survey). Hence, the plants in the second survey incur costs for the options analyzed above much less frequently than those in the first survey. Based on this evidence, and the fact that the search for plants in the second survey was quite thorough, it is believed that very few plants that would incur costs are omitted, and that the magnitude of the omitted costs is small.

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* U.S. Department of Commerce, U.S. Industrial Outlook 1982. The number of establishments assumes no changes from 1977.

Treatment Cost to Plant Sales Method

This method involved comparing the treatment cost to the plant sales. The primary obstacle was to find sales estimates for the 146 direct and indirect dischargers which were not included in the EIS pharmaceutical data base. Various methods were examined and discarded in favor of a regression analysis relating plant sales to plant manufacturing employment. The method is described in detail in Appendix A of this report. However, manufacturing employment data came from the 308 Surveys and were valid for 1975-1976 or 1977-1978. EIS provided plant sales estimates for 1979. This casts some doubt on the estimates yielded by the regression equations as the dependent and independent variables do not match with regard to year. In addition, many large pharmaceutical plants also had other product lines operating--usually organic chemicals, pesticides, and flavor and fragrance chemicals. The EIS sales estimates for these plants included the non-pharmaceutical sales as well. Therefore, a number of plants had overestimated sales which probably resulted in a shift of the predicted regression line. In addition to this systematic bias, there is error about the predicted sales due to random factors. Most likely this error is small compared to that introduced by the previous two problems. Another relatively minor source of error may be the use of an average inflation factor to inflate plant sales from 1979 to 1980 dollars.

A sensitivity analysis was conducted and consisted of replacing the regression estimated sales with their lower 90 percent confidence interval end points, and cost-to-sales ratios were again calculated. No new plants were added to the potentially impacted group, because no additional plants had revised cost-to-sales ratios of greater than 1 percent. Thus, despite the data problems inherent in the regression approach, the final results do not seem to be very sensitive to differences in sales estimates. This is due to the "tight" confidence intervals about the mean predicted responses, which are due to the large sample size.

Individual Plant Assessments

The limitations of the methods used to calculate the cost-to-sales screening ratio have been discussed above. Due to the uncertainties arising from these limitations, the cut-off levels for the screening measure has been set fairly low. The cost-to-sales ratio can not be considered a sufficient condition for identifying impacted plants. It is a tool to identify a set of plants which might suffer a significant impact, while not excluding any significantly impacted plants.

If sufficient plant-specific financial information were available to determine the actual operating costs of each plant, the output levels of the specific items produced, the ability of the plant to expand production or alter product mix, and the financial and production relationships among plants owned by a single firm then this screening procedure would not be necessary. In its place, a model of the industry could be constructed and the relative and absolute impact of the regulation on each plant could be estimated. Instead, similar but less specific and detailed information has been collected for each plant and its parent firm identified by the screening measures. The actual impact on the plant has been estimated based on the data available. However, the quality and quantity of information regarding market/product strength and financial success vary significantly among the plants identified. Therefore, the confidence level in certain plant-specific estimates may be low, but the overall assessment--that in general these proposed regulations will have only a small effect--remains.

Appendix A

Estimation of Pharmaceutical Plant Sales

In order to estimate the economic impacts on individual pharmaceutical plants and the industry in general, it was necessary to estimate sales for 146 of the plants. The data base was examined and regression equations relating sales to employment were determined.

A data base of 235 pharmaceutical direct and indirect dischargers was compiled from the data supplied by the Technical Contractor and from the Economic Information Systems (EIS) data base. The EIS data base provided 1979 sales estimates for each plant. The Technical Contractor assigned a code to every plant indicating which of the four major types of production processes were carried out there. These four groups of production processes, called production subcategories, are fermentation, biological and natural extractions, chemical synthesis, and formulation. Employment (number of manufacturing employees) and direct and indirect waste flow estimates were available for almost all plants from the Technical Contractor.

For the purposes of this analysis, combinations of production subcategories were classified into four groups. Group 1 consisted of all plants that used fermentation processes (subcategory A). Group 2 consisted of all plants that used biological extraction processes (subcategory B), not including those in Group 1. Plants using chemical synthesis (subcategory C), but not in groups 1 and 2, were classified as Group 3, and plants that were formulators only (subcategory D) were placed in Group 4. Table A-1 provides a summary of the plant characteristics of each group.

This method of grouping plants was chosen because it preserved some distinctions between production technologies and agreed with some important relationships in the data. For example, all but one of the plants using fermentation processes had wasteflows larger than 1 million gallons per day (MGD), while all other production processes had much smaller wasteflows. Typically, plants with fermentation processes produced more wastewater, had more employees and greater revenues than plants that did not use fermentation. Cross-tabulations of production subcategory versus sales, employment, and wasteflow and the summary statistics by production subcategory demonstrated that the three types of synthesis processes were better indicators of sales, employment and wasteflow than the formulation processes. This was the basis for defining Groups 2, 3 and 4.

Various regression models linking sales to employment and wasteflow within each group were investigated. Both log-transformed and untransformed data were used. Correlation analysis by group indicated

Table A-1. Summary Statistics of Regression Data Base Plant Characteristics

Group*		1979 Sales** (1,000 $)	Employment (Manufacturing*** Employees)	Sales to Employment Ratio (1,000$/ Employee)	Direct Flow*** (MGD)	Indirect Flow*** (MGD)
1	Mean	123648	1109	185.9	2.145	.519
	Std. Dev.	156984	1516	120.9	2.529	.854
	Median	68700	450	153.0	1.216	.124
	N	21	21	21	6	14
2	Mean	48966	281	470.9	.059	.173
	Std. Dev.	76393	587	631.9	.071	.496
	Median	14600	65	177.3	.027	.007
	N	44	43	43	6	33
3	Mean	54732	210	1000.7	.151	.216
	Std. Dev.	91389	357	1910.7	.265	.341
	Median	18000	60	295.0	.035	.053
	N	38	36	36	9	20
4	Mean	42256	220	628.6	.104	.024
	Std. Dev.	76712	479	1179.6	.145	.064
	Median	11300	52	229.7	.030	.001
	N	132	130	130	11	79

*Group 1: All plants using fermentation processes.
Group 2: All plants using biological extractions but not fermentation.
Group 3: All plants with chemical synthesis but not fermentation nor extraction.
Group 4: All plants which are formulators only.

**Source: Economic Information Systems.

***Source: Technical Contractor; some plants have 1976 employment while others have 1978 employment.

that log-transform models between sales and employment were the most promising. Other models associating sales and wasteflow and untransformed sales and untransformed employment were clearly inferior in terms of R-squares. The model for Group 1 was:

$$\ln(\text{sales}) = a + b*\ln(\text{employment}),$$

while the model for the remaining groups was:

$$\ln(\text{sales}) = a + b*\ln^2(\text{employment}).$$

The regression equations had R-squares ranging from 0.42 to 0.63. However, the differences between the observed sales and the estimated sales (back-transformed from their logarithims) were very large--as much as 600 percent difference. This is further evidence that small residuals between the transformed variables do not necessarily indicate small residuals between the back-transformed variable. Such error was unacceptable.

After examining plots of sales versus employment (and ln (sales) versus ln (employment)), several extreme outliers were discovered. Typically, these outlying plants had a very small or very large sales to employment ratio. When these plants were removed from the regression data base, the R-squares improved dramatically. Justification for these exclusions can be found by considering the sales data source: the EIS data base. EIS generally classifies a plant under one SIC code, even if many products not found under that SIC code are produced there. Consequently the sales estimate for that plant includes revenues from other SIC group products and, since the employment is the number of manufacturing employees, the sales/employment ratio can be deceptively large. Usually, the very large plants fit this description. Also, because the sales estimates are for 1979 and the employment estimates are from the 308 Survey data, which was done in 1976 and 1978, several sales/ employment ratios are not what would be expected due to unknown changes in employment over the three (or one) year period. Several plants surveyed in 1976 were scheduled to start up in 1977 and so agreement between that employment figure and the recent sales estimate should not be expected.

All plants with sales to employment ratio less than $70,000/employee were removed from the regression data base. This was approximately the 10 percent quantile (i.e., 10 percent of the plants had sales/employment ratios less than 70,000) for Groups 1, 2 and 4. This figure was chosen since it contained nearly all the outliers found on the plots. Additional plants with excessively high or inconsistent sales/employment ratios were removed from Groups 3 and 4. Both indirect and direct plants removed are listed in the following table.

Table A-2. Plants Removed from Regression Data Base

Group	# Excluded	# of Plants in Old Regression Data Base
1	2	21
2	4	43
3	4	36
4	14	130
Total	24	230 5 plants out of 235 have no employment estimates.

The results of the regression analysis are shown in Table A-3. Two different models were used:

$\text{sales} = a + b*(\text{employment})$ for Groups 1 and 3, and

$\ln(\text{sales}) = a + b*\ln^2(\text{employment})$ for Groups 2 and 4.

Initial analysis showed that the equations for Groups 2 and 4 were virtually identical, so the two groups of plants were pooled and another regression equation was calculated.

After calculating the differences between observed sales and estimate sales for Groups 2 and 4, it was evident that the regression equation generally underestimated sales for these groups, thereby yielding a relatively conservative estimate of sales in regard to the forthcoming economic impact analysis. The elasticity of sales with regard to employment for this model ranged from 0.11 to 1.41. The equations for Groups 1 and 3, on the other hand, have constant elasticities.

In Section 5, cost-to-sales ratios are expressed in 1980 dollars. Hence, the 1979 sales estimates generated using the equations of Table A-3 are escalated to 1980 using an inflation factor of 1.095. In Section 6, the ratios are calculated in 1982 dollars, but the 1979 sales are escalated to 1982 using a factor of 1.262. The escalation factors are based on the wholesale price index for pharmaceuticals.

Table A-3. Regression Results (sales in 1,000's of 1979 $)

Group	Model	R^2	a (t)⁺	B (t)	N
1	sales = a + B * employment	.95	8109.94 (.77)	144.61 (18.94)	19
2&4	ln(sales) = a + B * $\ln^2$(employment)	.71	8.12 (82.91)	0.08 (19.56)	155
3	sales = a + B * employment	.83	11166.32 (2.04)	170.50 (12.25)	32

⁺(t) - is the t-statistic for testing whether the estimated parameter is significantly different from zero. Except for the y-intercept estimates for Groups A and C, all parameters were significantly greater than zero at the 99.9% confidence level. The problems with the intercept estimates are due to clustering of data points near the origin.

Appendix B

Detailed Descriptions of Product Group

The following is an elaboration of the product group discussion in Section 3. The value of shipments for each of these product groups is presented in Table B-1 (duplicate of Table 3-12).

Preparations Affecting Neoplasms, Endocrine System and Metabolic Diseases

This group includes a fairly diverse number of pharmaceutical products. Shipments of $900 million were recorded in 1977, which accounts for 9.2 percent of the final products shown in Table B-1. Value of shipments increased 7.9 percent annually while shipments for all eleven groups grew 9.3 percent annually.

Hormones accounted for more than 75 percent of total group shipments. Secreted by the endocrine glands (thyroid, pituitary, gonads, and others) and present only in minute quantities, natural hormones regulate the body's metabolic activities. Hydrocortisone, androgens, estrogens, and progestogens are examples of steroid hormones. Corticotropin and insulin are nonsteroidal hormones. Hormones shipments increased slowly at 5.3 percent annually from 1972 to 1977. While ten out of the 200 most prescribed drugs in 1980 were oral contraceptives, they grew at an annual rate of only 2.9 percent from 1972 to 1977. Topical and systemic corticoids (used as anti-flammatory agents) accounted for 30 percent of group ship- ments and show an average annual increase of 8.8 percent from 1972 to 1977. Insulin and antidiabetic agents, sex hormones (other than progest- ogens and thyroid and antithyroid preparations) all had shipment increases well below the industry average. Antineoplastic agents, used to treat cancerous growths, grew 21.2 percent annually from 1972 to 1977. This subgroup includes radio-isotopes for internal use and specific antine- oplastic agents.

In summary, this product group has exhibited a lower than average rate of increase in shipments, with only antineoplastic agents showing a growth rate well above the industry average.

Preparations Affecting Central Nervous System and Sense Organs

Value of shipments for this group accounted for 22 percent of shipments for all product groups, the largest of all groups. Shipments increased only 6.4 percent annually from 1972 to reach $2.231 billion in 1977. Important subgroups are internal narcotic and non-narcotic analgesics and antipyretics, psychotherapeutic agents, Central Nervous System

Table B-1. Pharmaceutical Final Product Class Value of Shipments (current dollars)

Product Class	Value of Shipments (Millions of Dollars) 1977	Value of Shipments (Millions of Dollars) 1972	Uniform Average Increase (Percent)
Preparations affecting neoplasms, endocrine system and metabolic diseases	900	615	7.9
Preparations affecting central nervous system and sense organs	2231	1636	6.4
Preparations affecting cardiovascular system	751	400	13.4
Preparations affecting respiratory system	896	561	9.8
Preparations affecting digestive and genito-urinary systems	1074	746	7.6
Preparations affecting the skin	621	344	12.5
Vitamins, nutrients and hematinics	1302	587	17.3
Preparations affecting parasitic and infectious diseases	1285	948	6.3
Preparations for veterinary use	354	214	10.6
Blood and blood derivatives for human use	243	126	14.1
Active and passive immunization agents and therapeutic counterparts	126	89	7.2
Total	9783	6266	9.3

Source: 1977 U.S. Census of Manufactures Report (Current Industrial Reports figures).

(CNS) stimulants, sedatives and hypnotics, anesthetics, and eye and ear preparations.

Analgesics reduce awareness of pain without loss of consciousness; antipyretics help lower body temperature. The narcotic analgesics include morphine and its derivatives, synthetic morphine-like drugs and synthetic moieties of morphine molecules. Shipments of narcotic analgesics were valued at $172 million in 1977, showing an annual increase since 1972 of 13.2 percent. Nonnarcotic analgesics, which include aspirin, phenacetin, and acetaminophen, had 1977 shipments of $746 million with an average annual increase since 1972 of only 5.3 percent. Aspirin, aspirin combinations and other salicylates yielded $391 million in shipments. Aspirin alone had a shipments increase of only 1.5 percent from 1972 to 1977. While the narcotic analgesics are all ethical drugs, most of the nonnarcotic are proprietary. Also included in this group are the nonhormonal antiarthritics.

Psychotherapeutic agents include antidepressant drugs and tranquilizers. Shipments in 1977 were $754 million, increasing annually at 4.9 percent since 1972.

Amphetamines, a major subgroup of CNS stimulants, typically are used to reduce fatigue or appetite (anti-obesity drugs). Amphetamine shipments decreased 8.4 percent annually from 1972 to 1977. Stimulants as a whole grew at one percent annually during the same period.

Sedatives and hypnotics (sleep inducing agents) had $97 million in 1977 shipments increasing only 2.6 percent annually since 1972. This slow growth rate is in part due to the introduction of a number of new nonbarbiturate drugs in the late 1970s.

General and local anesthetic shipments grew 8.6 percent annually from 1972 to reach $88 million in 1977. All growth in this subgroup has been in local and topical anesthetics.

Eye and ear preparations have seen the highest growth in shipments (11.6 percent) after the narcotic internal analgesics. Total shipments were valued at $103 million in 1977. Miotics, agents that cause the pupil to contract, mydriatics, agents that dilate the pupils, and contact lens solutions are included in this subgroup.

In summary, while it is the largest product group in terms of value of ship- ments , it is one of the slowest growing. Only narcotic analgesics have been growing faster than the industry average.

Preparations Affecting the Cardiovascular System

This group of products had the second highest rate of shipments increase of all eleven groups with an annual rate of increase of 13.4

percent. Total 1977 shipments were $751 million, while 1972 sales were $400 million. This drug market appears rather promising because a number of new drugs with far-ranging possibilities, notably calcium and beta blockers, have entered the market in recent years.

Anticoagulants are agents that delay or counteract blood coagulation and are used to reduce or prevent blood clot formation within blood vessels. Shipments in 1977 were valued at $35 million, having grown 15.0 percent annually since 1972. Hypotensives help control hypertension and its effects, particularly high blood pressure. The major hypotensives contain rauwolfia compounds derived from an herb. Total 1977 value of shipments for hypotensives (the largest subgroup within this group) was $335 million, and increased at 13.7 percent annually from 1972 to 1977.

Vasodilators induce smooth and cardiac muscle relaxation and dilate the blood vessels. Shipments in 1977 were estimated at $156 million, having increased only 4.5 percent annually since 1972.

The last major subgroup includes vasopressors, antiarrhythmics and antiheparin agents. Vasopressors constrict blood vessels and thus raise blood pressure. Antiarrhythmics help slow the irregular, rapid heartbeats knows as arrhythmias (a potentially fatal condition for those with weak or diseased hearts). The beta and calcium blockers are perhaps the most important new drugs in this group. Calcium blockers prevent calcium and minerals from entering muscle tissues and thus ease the pain of angina. Calcium blockers have fewer side effects than beta blockers, which try to influence the hormonal system that can speed up the heart and other organs' action in times of stress. Shipments in 1977 for this subgroup were $201 million, with a growth rate of 25.3 percent annually, from 1972 to 1977.

In summary, this product group has been experiencing very rapid growth in shipments, with vasopressors, antriarrhythmics and antiheparin agents increasing the fastest.

Preparations Affecting the Respiratory System

This product group's shipments increased 9.8 percent annually from 1972 to 1977, slightly above the overall pharmaceutical industry average of 9.3 percent. The largest subgroup--cold preparations, both ethical and proprietary, without antitussives--grew only 7.4 percent annually. This subgroup had $518 million in shipments in 1977 and represented 58 percent of respiratory system product sales. The category includes nasal decongestants, nose drops, lozenges, and antihistamines. Cold preparations include combinations of antibiotics, nasal decongestants, antihistamines, analgesics, and bioflavanoids. Bronchial dilators, agents that open the lungs, bronchi, and bronchial tubes making breathing easier, and cough preparations, both narcotic (those with codeine) and non-narcotic, had shipments increases greater than the pharmaceutical industry average.

Antihistamines are complex amines that prevent the buildup of histamines in body tissues and are typically used for treatment of allergenic diseases. They are also used in nasal and ophthalmic decongestants, sleep inducers, and antipruritics (for relief of itching). Shipments growth of antihistamines, except those in cold preparations, was just 4.0 percent annually from 1972 to 1977 and represented only a small portion of the $896 million of respiratory shipments.

Preparations Affecting the Digestive and Genito-Urinary Systems

This product group accounted for just over a billion dollars in value of shipments in 1977 and represented 11 percent of the product mix. Antacids, the largest subgroup in this category with $300 million in 1977 shipments, have experienced growth of 0.6 percent annually since 1972. Antacids reduce excess gastric acidity by several methods: neutralization; buffering; a combination of absorption, buffering and partial neutralization; or ion-exchange. Sodium bicarbonate, sodium citrate, sodium acetate, magnesium oxide, calcium carbonate, and aluminum hydroxide gel are common active ingredients in antacids. While antacids are proprietary drugs, roughly 65 percent of all products in this group are ethical. Laxative shipments increased much less quickly with an annual percentage increase of 4.3 percent. Still, they represent 15 percent of the digestive and genito-urinary shipments. For both antacids and laxatives there is intense competition and the rising costs of advertising will become an important factor in sales growth in the near future. Phenolphthalein, castor oil, magnesium sulfate, milk of magnesia, agar, methylcellulose, mineral oil, dioctyl sodium, and calcium sulfosuccinates are all active ingredients in laxatives. Antispasmodics and anticholinergenics are drugs that relax involuntary (smooth) muscles and help relieve discomfort from peptic ulcers and asthma.

Diuretics, agents that promote urine excretion, are an important growth market. In 1977, $215 million worth of diuretics were shipped, exhibiting a growth of 9.0 percent annually since 1972. Nearly all the major pharmaceutical manufacturers make or market one or more of these compounds. While diuretics increase urine, sodium, and chloride excretion, many also promote potassium excretion. Perhaps the biggest area for sales growth is with "potassium-sparing" diuretics. A number already exist with others slated for release soon.

The subgroup with the largest percent increase in shipments is the contraceptive agents (not including oral contraceptives) subgroup. Shipments increased from $30 million in 1972 to $68 million in 1977--a rate of 17.8 percent a year. These figures include shipments for contraceptive foams, aerosols, and jellies.

Preparations Affecting the Skin

The value of shipments for this group increased 12.5 percent annually between 1972 and 1977 with $621 million in shipments in 1977. This rate is above the pharmaceutical industry average of 9.3 percent for the same period. Dermatological preparations, used for treatment of skin disorders, represented 63 percent of group shipments and increased 15.9 percent annually. Within this subgroup, antiacne and antiseborrehic preparations increased 22.5 percent annually in shipments. Other drugs contained in this group are hemorrhoidal preparations and external analgesics.

Vitamins, Nutrients and Hematinic Preparations

This group had 1977 shipments of $1.3 billion. It had the highest growth rate in the pharmaceutical industry (17.3 percent) and accounted for ten percent of the total product mix. Group shipments have been increasing strongly since the 1960s; the average annual growth in shipments from 1967 to 1977 was 13.4 percent.

Vitamins are necessary in small quantities for normal metabolism and are most often marketed as dietary supplements. They are also used medicinally to prevent or treat disease. Most of the vitamin production is by chemical synthesis. Bulk vitamins are formulated either as pills or capsules and are frequently used by the animal feed and food additive industries. From 1972 to 1977 multivitamin shipments increased annually at 16.9 percent. Nutrients, not including therapeutic dietary foods and formulations, increased in shipments 40.5 percent annually over the same period. General dietary supplements of calcium, protein and potassium and also infant formulas, such as Similac and Enfamil, are the major products of this subgroup.

Hospital solutions supply a patient with fluids, nutrients and electrolytes. Shipments of such products have increased 22.6 percent annually from 1972 to 1977. More than $380 million worth of these pro- ducts were shipped in 1977. Hematinics, agents that aid blood cell and hemoglobin formation, were the only major subgroup of products to experience a very low rate of sales increase--3.3 percent--in this group.

Preparations Affecting Parasitic and Infectious Diseases

Included in this group are amebicides, anthelmintics, antibiotics, tuberculostatic agents, antimalarials, sulfonamides, antifungal preparations, antibacterials, and antiseptics. In total 1977 shipments value this was the third largest, with $1.28 billion. Value of shipments growth has slowed to 6.3 percent annually from 1972 through 1977. Over 70 percent of total shipments value is due to shipments of antibiotics which grew 7.3 percent annually from 1972 to 1977.

Broad and medium spectrum antibiotics (not including penicillin) accounted for more than 66 percent of total antibiotics shipments; this subgroup includes tetracycline and its derivatives, erythrocin, cephalosporins, and chloramphenicol. Cephalosporins have seen a number of new developments in recent years. They are substances chemically related to penicillins but have a broader spectrum of activity and lower acute toxicities than penicillins. Penicillin shipments grew at a slower rate of 6.3 percent annually. Most likely shipments will continue to grow at a slow rate as more and more pathogens become resistant to penicillin. However, a number of popular antibiotics are semi-synthetic penicillins; the precursor to penicillin is produced by fermentation and then chemically altered to increase effectiveness.

Sulfonamides, or sulfa drugs, have been gradually replaced by antibiotics in treating bacterial infections, but shipments growth is above the group average, 7.4 percent annually. They are used in diuretics, hypoglycemics, and hemotherapeutics. Antibacterials and antiseptics have shown virtually no growth from 1972 to 1977, but represent 13 percent of value of shipments for the group in 1977.

Preparations for Veterinary Use

This group includes all health, vitamin and nutrient products formulated for veterinary use. There were over $350 million worth of shipments in 1977 representing approximately three percent of total shipments for all eleven product groups. Average annual growth from 1972 to 1977 was 10.6 percent. Most of the subgroup had little or no growth, but antibiotics shipments grew at 12.0 percent annually and hormone shipments increased 18.6 percent annually. Together they accounted for 46 percent of group shipments.

Blood and Blood Derivatives for Human Use

Included in this group are whole human blood, blood plasma, normal blood serum, and other blood fractions. Total shipments in 1977 were $243 million, having increased 14.1 percent annually since 1972.

Preparations for Active and Passive Immunization and Therapeutic Counterparts

Total 1977 shipments for this group were $126 million, having shown an average annual increase of 7.2 percent since 1972. Toxoids, antigens, and viral vaccines are used in active immunization. An active immunization agent alerts the body's immunological defense system and causes it to form antigens and antibodies to deal with a possible future pathogen. Passive immunization agents, like antitoxins, help the body deal with a pathogen that has breached the body's defenses. Antivenins, antitoxins, immune globulins, and immune serums are agents of passive immunization.

Other Products

Product types in SIC 2831 not included in the eleven groups above are active and passive immunization agents for veterinary use and diagnostic substances (allergenic extracts and other biologicals). Total 1977 shipments for these product groups was $570 million.

Appendix C

Capital Recovery Factor

The capital recovery factor (CRF) measures the rate of return that an investment must achieve each year in order to cover the cost of the investment and maintain net earnings, including depreciation and taxes. Stated another way, the capital recovery factor is the excess of revenues over variable costs, per dollar of invested capital, needed to cover the cost of borrowing, depreciation and net profit-related taxes, while preserving the market value of the firm's stock.

The formula for CRF used in previous analyses* was:

$$\mathrm{CRF} = \frac{A(N,K_f) - td}{1 - t} \qquad \text{(C-1)}$$

where:

N = lifetime of investment

K_f = average after-tax cost of capital

$A(N,K_f)$ = annuity whose present value is 1, given N and K_f $[K_f/(1-(1+K_f)^{-N})]$

d = depreciation rate

t = corporate income taxes

Changes in the tax code dealing with rapid depreciation and investment tax credits require alterations in the formula for calculating the capital recovery factor. The revised formula is:

$$\mathrm{CRF} = \frac{A(N,K_f)(.9-c)}{1 - t} \qquad \text{(C-2)}$$

where: $$c = \mathop{}_{j=1}^{n} \frac{td'}{(1+K_f)^j}$$

where:

n = depreciation lifetime under tax code

d' = new depreciation rate

Other variables as above.

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* Economic Impact Analysis of Effluent Limitations and Standards for the Pulp, Paper and Paperboard Industry, Meta Systems Inc, EPA Contract 68-01-6162, September 1982.

The assumptions and data used to obtain values for the above variables are described below.

Average Cost of Capital

The cost of capital, K_f, is the average percentage return that suppliers of debt and equity demand. For firms which have more than one type of capital, K_f is calculated as the average of the after-tax costs of debt and the costs of equity, weighted by the share of market value of each relative to the total market value of the firm. In equation form:

$$K_f^* = bi(1-t) + (1-b)r \qquad \text{(C-3)}$$

where:

K_f^* = average cost of capital after taxes
i = average cost of debt
r = average cost of equity
t = corporate income tax rate
b = share of debt financing

The costs of debt and equity are measured by the current market value of outstanding debt and stock, rather than the original costs when the debt and equity were issued. The argument that projects should be evaluated using the weighted average cost of capital as the discount factor has been made elsewhere* and rests on several assumptions. Firms are assumed to have an optimal debt/equity ratio (or at least some preferred debt/equity ratio), to have already obtained that ratio, and to strive to maintain it over time. In addition, it is assumed that new projects do not alter the overall risk position of the firm. (A change in the risk level might result in a change in the debt/equity level.) Therefore, new projects, on average, will be financed with these same desired fractions of debt and equity.

Cost of Debt. Since firms often have more than one debt issue, it is necessary to calculate an average cost within a company as well as across companies. The following information on the debts of 40 chemical companies was obtained from Standard and Poor's Bond Guide (August 1979).*

1) yield to maturity
2) debt outstanding
3) closing price

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* See, for example, J. Fred Weston and Eugene F. Brigham, Managerial Finance (6th ed.), Dryden Press, 1978, Chapter 19.

First, the total market value of each bond issue is calculated as the bond price multiplied by the amount of debt outstanding. Second, the average cost of debt is calculated as a weighted average of the various values for yield to maturity, where the weights equal the ratio of the market value of each bond issue to the total value of debt. The average before-tax cost of debt for these companies is 9.89 percent.

Cost of Equity. A firm's cost of equity can be expressed in equation form as:

$$r = \frac{e}{P} + g \qquad \text{(C-4)}$$

where e is the annual dividend, P is the stock price, and g the expected growth rate of dividends.** To estimate the firms' cost of equity, the following data were obtained from Standard and Poor's Stock Guide (August 1979):

1) dividend yield;
2) closing price;
3) number of shares outstanding.

Information was collected for common stocks. The existence of preferred stocks complicates the calculations substantially, since a preferred stock is more nearly a stock-bond hybrid. Preferred stocks are ignored except where they represent more than 10 percent of the market value of all stocks. In those cases where preferred stocks represent a significant portion of equity, the company was removed from the survey.

An estimate of the expected growth rate was obtained using data from the USITC Organic Chemicals (1977) and the DRI Chemical Review. A weighted average of annual growth rates for plastics, fibers, and elastomers sales was obtained for the entire industry:

$$g = \underbrace{.745(.071)}_{\text{Plastics}} + \underbrace{.125(.016)}_{\text{Elastomers}} + \underbrace{.130(.038)}_{\text{Fibers}} = .06 \qquad \text{(C-5)}$$

Depreciation

Depreciation is normally defined as the fraction of revenues set aside each year to cover the loss in value of the capital stock. Due to recent changes in the Federal tax code, the economic life of a capital item is now considerably longer than the depreciation life for tax purposes. Based on earlier work the lifetime of capital stock for this industry is assumed to be about 10 years.* The depreciation rate for most personal property now is straight-line over five years (20 percent). These values are used in the revised calculation of the capital recovery factor.

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* It is assumed that the cost of capital to pharmaceutical companies is very close to that for chemical companies in general.

** See, for example, J. Weston and E. Brigham, op.cit.

Tax Rate

The current Federal corporate income tax rate is 20 percent on the first $25,000 of profits, 22 percent on the next $25,000, and 46 percent on all profits over $50,000. For this analysis, plants are assumed to be paying an even 46 percent Federal tax on all profits. A study by Lin and Leone** indicates that state and local income taxes also are a significant factor in pollution control investments. State corporate income tax rates may be as high as 9.5 percent. In their study, a weighted average of 7 steel-producing states yielded an average state corporate income tax rate of 7.55 percent. State income taxes, of course, are deductible expenses in computing corporate income tax. A state corporate income tax rate of 8 percent is assumed here. Deducting this figure before computing the Federal income tax rate reduces the net effect of the 8 percent rate to about 4 percent. Thus, the overall effective income tax rate is approximately 50 percent.

Sensitivity Analysis

Table C-1 presents various values for the capital recovery factor, assuming various weighted costs of capital (K_f) and different formulations allowing for changes in the Federal tax code. Both the rapid depreciation and the investment tax credit serve to lower the capital recovery factor, thus reducing the return necessary to justify a given investment.

The weighted cost of capital is estimated based on the current costs as reflected in the current prices and yields of a sample of corporate stocks and bonds for that industry. In August of 1979, the weighted cost of capital for the organic chemical industry was estimated to be about 10 percent. There are two major assumptions in using this method. First that current prices and yields accurately reflect future costs of capital. However, interest rates have increased significantly since the summer of 1979. Second, that the current portfolio mix will remain constant over the next several years. Given changes in tax codes, and changes in the availability of certain sources of capital such as industrial revenue bonds, this is unlikely. Therefore the cost of capital is expected to be higher than 10 percent. Given the mix of financing sources available, the weighted cost of capital for the period covered by this study is assumed to be close to 15 percent.

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*Draft Industry Description: Organic Chemical Industry, Vol. I, Meta Systems, December 1979.

**An Loh-Lin and Robert A. Leone, "The Iron and Steel Industry," in Environmental Controls, (Robert A. Leone, ed.), Lexington, MA: Lexington Books (1976), p. 70.

Table C-1. Alternative Derivations of the Capital Recovery Factor

Variable	Values						
Weighted cost of capital (K_f)	.10	.15	.20	.10	.13	.15	.20
Life of asset (N)	10	10	10	10	10	10	10
A(N, K_f)	.163	.199	.239	.163	.185	.199	.239
Depreciation life (n)	10	10	10	5	5	5	5
Depreciation rate (d)	.10	.10	.10	.20	.20	.20	.20
Tax rate (t)	.50	.50	.50	.50	.50	.50	.50
c				.379	.352	.335	.299
CRF(1)	.226	.298	.378				
CRF(2)				.201	.240	.265	.335
CRF(3)				.169	.202	.225	.288

where: CRF(1) is original formula (C-1 in text)
CRF(2) allows for rapid depreciation but not investment tax credit
CRF(3) allows for both rapid depreciation and investment tax credit (C-2 in text)

A single, industry-wide CRF equal to 22 percent has been used in our analysis. For a given investment, a firm's CRF will vary with their cost of capital and mix of financing. However, it was not possible to estimate a separate CRF for each establishment or firm.